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Pesticide Registration Standard

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Agency

Office of
Pesticides and Toxic Substances
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August 1981

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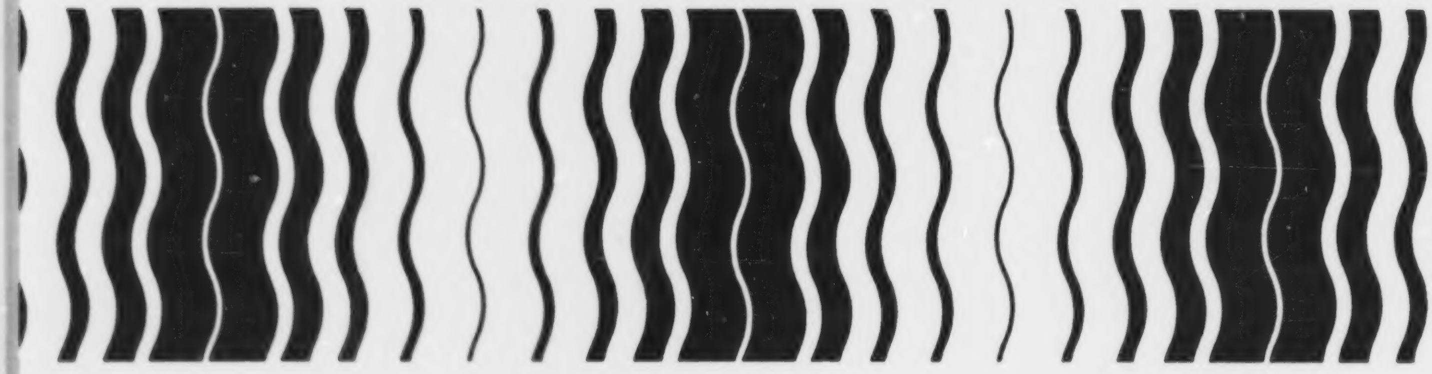
Pesticides

EPA

0,0-diethyl S-[(6-chloro-2-oxobenzoxazolin-3-yl-)methyl] phosphorodithioate (Phosalone)

Pesticide Registration Standard



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This document contains information regarding reregistration of pesticide products containing Phosalone, including how to register under the registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also include is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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Phosalone

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The changes are as follows:

Insert Table 1, page 55a.
Insert Table 2, Page 60a.

Delete the following two citations from the Office of Pesticide Programs Registration Standard Bibliography entitled "Citations Examined and Judged to be Inappropriate for Use in Developing the Standard":

000006386 Desmoras, J.; Laurent, M., Terlain, B; Aublet, J.C.; Sasmayoux, J.C.; Savary, M. (1966) Study of the Metabolism of Phosalone (11974 R.P.) in Plants: R.P.--D.S. Ph. No. 11686. (Unpublished study received February 2, 1967 under 7G0575; prepared by Societe des Usines Chimiques Rhone-Poulenc, submitted by Chipman Chemical Company, Inc., Burlingame, California; CDL; 090727-E)

000006674 Societe des Usines Chimiques Phone-Poulenc (1968) R.P.: Oxygen Analogue of Phosalone: Acute Oral Toxicity and Anticholinesterasic Activity in Vitro: R.P.--D.S. Ph. No. 12644. (Unpublished study received June 14, 1968 under 8F0668; Submitted by Chipman Chemical Company, Inc., Burlingame, California, CDL: 091170-B)

Phosalone

Pesticide Registration Standard

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August 21, 1981

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CHAPTER I: HOW TO REGISTER UNDER A REGISTRATION STANDARD

A. Organization of the Standard
B. Purpose of the Standard
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A. Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second chapter involves the regulatory position and the rationale supporting this position. The third chapter sets forth the data requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards.

B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"1. its composition is such as to warrant the proposed claims for it;

2. its labeling and other material required to be submitted comply with the requirements of this Act;

3. it will perform its intended function without unreasonable adverse effects on the environment; and

4. when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. However, the established approach to making these findings has been found to be defective on two counts.

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use the pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

C. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1. Data that are product specific , i.e. data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2. Generic data that pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products are also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concern the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed guidelines, 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed guidelines,43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered are all data which are described by all of the following criteria:

1. The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

2. The data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain an existing registration;

3. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

4. The Agency has found the data to be valid and usable in reaching regulatory conclusions; and

5. They are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a "product by product" basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

G. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

CHAPTER II: REGULATORY POSITION AND RATIONALE

A. Introduction
B. Description of Chemical
C. Regulatory Position
D. Regulatory Rationale
E. Criteria for Registration under the Standard
F. Required Labeling
G. Tolerance Reassessment

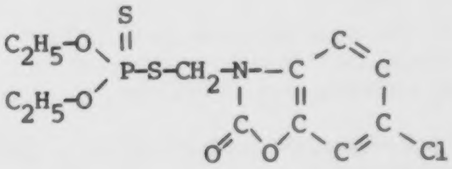
A. Introduction

This chapter presents the Agency's regulatory position and rationale based on an evaluation of all registered products containing phosalone as the sole active ingredient. After briefly describing the chemical, this chapter presents the regulatory position and rationale, the criteria by which applicants for registration of phosalone products will be approved, labeling considerations, and tolerance reassessment. A summary of data requirements is contained in Chapter III. A discussion of the data upon which this regulatory position is based is presented within the disciplinary chapters, IV through VIII. Also considered in this standard are Special Local Need (SLN) registrations, which are issued by a State in accordance with FIFRA section 24(c). Valid State registrations will be subject to reregistration under the EPA Registration Standard System, in the same manner as a registration issued under section 3 of FIFRA. Currently such a registration has been granted to California for the application by aircraft to almonds, grapes, stone fruits and walnuts.

B. Description of Chemical

Phosalone (0,0-diethyl S-[(6-chloro-2-oxobenzoxazolin-3-yl-)methyl] phosphorodithioate) is registered as an insecticide and miticide for use on a variety of fruit, nut, vegetable and ornamental crops. The Chemical Abstracts Service (CAS) Registry number is 2310-17-10. The OPP Internal Control Number (EPA Shaughnessy number) is 097701.

The structural formula is:



C. Regulatory Position

Phosalone as described in this Standard may be registered for sale, distribution, reformulation and use in the United States and its territories. The Agency has considered the scientific data obtained from the open literature as of July 1, 1981, and those data submitted by the registrants up through the time of publication of this Standard. Based upon the review of these data, the Agency finds that none of the risk criteria found in section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations were met or exceeded for phosalone. The Agency has determined that phosalone has not been demonstrated to cause unreasonable adverse effects, to either man or the environment, when used in accordance with prescribed label directions and precautions. Phosalone products currently registered may be reregistered subject to the conditions imposed by this chapter, and to the data requirements identified in Chapter III. New products may be registered under this Standard and are subject to the same requirements.

D. Regulatory Rationale

The Agency has reviewed data on phosalone concerning toxicology, ecological effects, residue and product chemistry, and environmental fate. The toxicological effects data base is reasonably complete, except for acute inhalation toxicity, primary dermal irritation, primary eye irritation, dermal sensitization, subchronic 21-day dermal, and acute delayed neurotoxicity data for the manufacturing-use product. Primary dermal irritation and dermal sensitization data are still needed for the end-use products. Data are also still needed for primary eye irritation for the wettable powder formulation. The residue chemistry data base is complete. There are some gaps in the data base for product chemistry, and environmental fate. Much of the data base is missing for ecological effects. Because there are no registered public health related uses, the Agency has waived the need for efficacy data to support the uses of phosalone. Despite the existing data gaps, the Agency has concluded that the registration for this chemical should continue for the following reasons:

1. No valid, adverse effects data of regulatory concern have been revealed in the review of the studies made available to the Agency. The Agency, therefore, has concluded that the known risks, as mitigated by product labeling, do not warrant any immediate adverse regulatory action.

2. Although phosalone has been implicated in a few poisoning incidents, the data do not conclusively indicate any hazards associated with the normal use of phosalone.

    a. The Pesticide Incidence Monitoring System (PIMS report) lists 12 incidents involving phosalone. However, eleven of these incidents could not conclusively implicate phosalone, because of excessive alcohol consumption, improper use of safety equipment, failure to follow recommended safety regulations, and other reasons. The one valid incident was isolated and did not indicate a consistent pattern of hazard associated with the recommended use of phosalone.

b. In 1973 there was a significant illness episode in Fowler, California involving 32 pickers, who harvested grapes more than one month after the application of phosalone, ethion, Imidan and dialifor. Although phosalone might have caused the cholinesterase inhibition symptoms, it is also important to consider the possibility of interactive potentiation, since these workers were exposed to more than one pesticide. Therefore, phosalone per se cannot be implicated as the sole cause of the symptoms (Maddy, K.T., 1976, MRID 005001833).

c. Another illness episode occurred in a vineyard near Madera, California. Cholinesterase depression and cholinergic symptoms were reported among 118 field workers harvesting grapes, which had been treated with dialifor and phosalone between 15 and 40 days earlier. The conclusion of this study indicates that the 21-fold difference in the toxicity of the two chemicals indicates that the effects were probably produced by dialifor and not by phosalone (Knaak et al., 1978, MRID 005003635).

3. In accordance with FIFRA, the Agency's policy is not to cancel or to withhold registration merely for the lack of data. (See Sections 3(c)(2)(B) and 3(c)(7) of FIFRA.) Rather, publication of the Standard provides a mechanism for identifying data needs, and registration under the Standard allows for upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency. The Agency will then determine whether these data will affect the registration of this chemical.

E. Criteria for Registration Under The Standard

To be subject to this Standard, products must meet the following conditions:

- contain phosalone as the sole active ingredient,
- bear required labeling, and
- conform to the product composition standard, acute toxicity limits, and use pattern requirements as discussed in the Manufacturing-Use and End-Use Product sections, which follow.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in this Standard, including a commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offering to pay compensation to the extent required by 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide

Act (FIFRA), as amended, 7 U.S.C. 136a(c)(1)(D). As discussed in Chapter I, applicants for registration under this Standard should contact the Agency for specific instructions, including updated information on data requirements and companies whose data must be cited and to whom compensation must be offered.

1. Manufacturing-Use Products

   a. Product Composition Standard

To be covered under this Standard, manufacturing-use products must contain phosalone as their sole active ingredient. Such formulations must contain contain 94 percent active ingredient. Each formulation proposed for registration must be fully described within an appropriate certification of limits.

   b. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use products containing phosalone regardless of the toxicity category, provided that the labeling of such products bears appropriate precautionary statements.

   c. Use Patterns

To be covered under this Standard, manufacturing-use only products of phosalone must be labeled to allow for formulation only into end-use insecticides/ miticides, which are intended for uses accepted by the United States Environmental Protection Agency.

2. End-Use Products

   a. Product Composition Standard

Emulsifiable concentrate (EC) phosalone products containing 34.4 percent (3 pounds per gallon) active ingredient or less and wettable powder (WP) formulations of 25 percent active ingredient or less will be considered under this standard.The appropriate certification of limits must be provided and the application rates on a per acre basis must remain the same or be less.

   b. Acute Toxicity Limit

The Agency will consider for registration end-use products of any toxicity category. This acceptance, however, is predicated upon label incorporations of appropriate hazard warnings, as well as precautionary and use restrictions as required.

c. Use Pattern

To be considered under this standard, end-use products must bear directions for use as an insecticide/miticide, which are intended for outdoor commercial, ground and aerial applications (food or nonfood uses). The use pattern of this insecticide/miticide may be expanded to include outdoor domestic, ground application (food or nonfood uses), if the product is in child-resistant packaging as described in 40 CFR 162.16. Sites of application include apples, apricots, artichokes, cherries, grapefruit, grapes, lemons, nectarines, nuts, oranges, peaches, pears, potatoes, prunes, arborvitae, and roses.

F. Required Labeling

All manufacturing-use and end-use phosalone products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package which accompanies this standard contains specific information regarding label requirements.

The following antidote information should also appear on all labels:

> "Causes cholinesterase inhibition. Atropine is antidotal. 2-PAM is also antidotal and may be administered in conjunction with atropine. Warning symptoms include weakness, headache, tightness in the chest, blurred vision, nonreactive pinpoint pupils, salivation, sweating, nausea, vomiting, diarrhea, and abdominal cramps."

The registrant may submit an alternative antidote statement for Agency consideration.

Additional label restriction statements, grouped by manufacturing-use and end-use products, are as follows:

1. Manufacturing-Use Products

All manufacturing-use product labels must bear the following statement:

> "For Formulation into End-Use Insecticide/Miticide Products Intended Only for Uses Accepted by the United States Environmental Protection Agency."

2. End-use Products

a. Human Hazard Precautionary Statements

1). All EC products must require the use of goggles in their warning statements, because of the high acute eye irritation hazard. (Please refer to Chapter VI on toxicology for a discussion.)

2). The Agency is currently developing Guidelines for reentry intervals. In addition the Agency is currently reviewing the 24 hour reentry interval, which was established in 40 CFR 170. (Please refer to Chapter V for a detailed discussion.) Until the Guidelines and reentry interval review are complete, the Agency will require a 24 hour reentry interval. Therefore, the following statement must appear on the label:

> "Reentry into treated fields is prohibited within 24 hours of application."

b. Environmental Hazard Statements

Sufficient information is available to consider phosalone as being of low to moderate toxicity to pollinators. This toxicity may be mitigated, if phosalone is applied when the pollinators are not foraging. Therefore, the following statement must appear on all labels:

> "This product is toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees are visiting the treatment area."

c. Additional Labeling

These statements are required in addition to those standard precautionary statements outlined by the guidance package.

1). Because the Agency lacks supporting acute human health effects and environmental fate data, the following statement must appear on the label.

> "This product is not for use in greenhouses."

2). Because phosalone meets the criteria established in the child-resistant packing regulations (40 CFR 162.16), all products must be packaged in such containers, unless the following restriction appears on the label:

> "For agricultural or commercial use only."

3). There are data concerning the accumulation of phosalone in rotational crops, which indicate that phosalone and/or its metabolites are taken up by radishes, beans, potatoes, and wheat under greenhouse conditions (Ambrosi et al., 1977, MRID 000006664). Therefore, the Agency has determined that a crop rotation restriction must appear on the label as follows:

> "Do not use in crop rotation programs."

As an alternative to this label restriction, the registrant may choose to pursue any one of the following three options:

a). Supply environmental fate data supporting a rotation interval which does not result in a pesticide residue in the rotated crops; or

b). Obtain a tolerance for the nontarget crop (46 FR 3018); or

c). Obtain an exemption from a tolerance for the nontarget crop.

In the interim, however, the label amendment described previously will be required.

4). Because of the potential toxicity to animals shown by the animal metabolism data and residue information in Chapter VII, the following must appear on the label:

> "Do not allow livestock to graze cover crops in orchards or nut groves treated with phosalone. Do not feed cover crops treated with phosalone to livestock."

G. Tolerance Reassessment

A listing of the tolerances for residues of phosalone in or on raw agricultural commodities as stated in 40 CFR 180.263 and 21 CFR 193.340 is found in Chapter VII.Data summarized in this standard support these tolerances.

A report by the Food and Drug Administration shows that under the FDA Regulatory Enforcement Program during the Fiscal Years 1977 thru 1980 approximately 1,480 agricultural crops were sampled and analyzed. About 86 of these samples showed the presence of small amounts of phosalone. None of the reported residues exceeded the residue tolerance levels established for phosalone for these crops. A summary of EPA estimated daily intakes of phosalone based on these data in terms of mg/kg of body weight/day is reported as follows:

	FY 1973	FY 1974	FY 1975	FY 1976
phosalone	0.000002	0.00002	0.00004	0.000001

A list of the CODEX Tolerances is also found in Chapter VII. The CODEX tolerance for pecans and chestnuts (nuts) is 0.1 ppm, while the U.S. tolerance for all nuts (including pecans and chestnuts) is 0.05 ppm. Both tolerances are based on the sensitivity of the method used. In accordance with Agency policy of cooperation with FAO/WHO and the Codex Alimentarius Commission, and to eliminate possible barriers to international trade, the Administrator will initiate the change of 0.05 ppm to 0.1 ppm for pecans and chestnuts (nuts) under the authority of the Federal Food, Drug and Cosmetic Act, Section 408 (e) and 40 CFR 180.32. Since there would be an insignificant change in the present Theoretical Maximum Residue Concentration (TMRC), this would make the U.S. tolerance consistent with the CODEX tolerance. The TMRC is based on established tolerances for phosalone residues in or on raw agricultural crops. The U.S. registered uses for all other crops indicate it would not be advisable to change their tolerances.

In calculating the TMRC the Agency assumes that the chemical is applied to all commodities on which its use is authorized, that each commodity contains the maximum level allowed in the tolerance, and that average 60 kilogram adult eating patterns result in 100 percent of the phosalone-treated food in the adult diet of 1.5 kilogram per day.

Based on the published tolerances for phosalone in all crops for which it is registered, the theoretical maximum residue concentration (TMRC) is 1.0107 milligram per day for a 1.5 kilogram diet for 13.5 percent of the maximum permissible intake (MPI). The TMRC for all eleven registered nut crops is 0.00022 milligram per day. If the tolerance is increased from 0.05 to 0.10 ppm, the nut TMRC will be doubled to 0.00044 milligram per day, and the new total TMRC will be 1.0109 milligram per day. Increasing the TMRC from 1.0107 to 1.0109 will result in virtually no change in the percentage ADI. The increase is approximately 0.02 percent of the ADI. The revised TMRC (1.0109 milligram per day) is 0.0168 milligram of phosalone per kilogram body weight per day for a 60 kilogram person. Therefore, there are no toxicological reasons for objecting to the revision of 0.05 ppm tolerance in nuts to 0.1 ppm.

To calculate the Acceptable Daily Intake (ADI) for the purpose of assessing the toxicological significance of revising tolerances, a no-observed-effect-level (NOEL) of 25 ppm is taken from the two-year rat feeding study (Woodard et al., 1967, MRID 000006202). This is equivalent to a 1.25 milligram per kilogram per day NOEL. Using a safety factor of ten (for extrapolation from a chronic study in rats to man with respect to cholinesterase inhibition), the acceptable daily intake (ADI) is 0.125 milligram per kilogram per day (determined by dividing the NOEL in milligram per kilogram by ten). The MPI is determined by multiplying the ADI by 60 kilogram (assumed average body weight for humans), and is 7.5 milligram per person per day.

The tolerance for nuts was the only one for which a change was accepted. All established tolerances are considered adequate to protect public health.

CHAPTER III: SUMMARY OF DATA REQUIREMENTS AND DATA GAPS

A. Introduction
B. Table A - Generic Data Requirements
C. Table B - Product Specific Manufacturing-Use Products Data Requirements
D. Table C - Product Specific End-Use Product Data Requirements

A. Introduction

Applicants for registration of manufacturing-use and end-use phosalone products must cite or submit the information identified as required in the tables in this chapter. The tables applicable to end-use products indicate whether the product to be tested is the technical grade or formulation. Data generated on one formulation may be used to satisfy the data requirement for a substantially similar formulation. Information on which product specific data requirements are already met is available in the guidance package.

Before each requirement is listed the section of the Proposed Guidelines which describes the type of data and when the data are required to be submitted [43 FR, 29696 of July 10, 1978; and 43 FR, 37336 of August 22, 1978; 45 FR, 72948 of November 3, 1980]. Justification for the test requirement is provided in the Guidelines. A discussion of why data additional to those already submitted are necessary, or why data normally required are not necessary for this chemical, is explained in footnotes to the tables. The data requirements specified are the minimum that will be required. Areas where additional data may be required as the result of tiered testing are indicated.

Table A: Phosalone
Generic Data Requirements: Environmental Fate (See Chapter V)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.62-7(b)	Hydrolysis	Tech. or Radiolabeled Analytical Gr.	partially[1]	Laurent et al., 000006067	yes/12 mo.
163.62-7(c)	Photodegradation	Tech. or Radiolabeled Analytical Gr.	yes	Ambrosi et al., 000006409 Ambrosi et al., 000006666 Laurent et al., 000006665	no
163.62-8(b)	Aerobic Soil Metabolism	Tech. or Radiolabeled Analytical Gr.	yes	[2]	no
163.62-8(c)	Anaerobic Soil Metabolism	Tech. or Radiolabeled Analytical Gr.	no	-	yes/14 mo.
163.62-8(f)	Microbial Metabolism:				
	(2) Effects of Microbes on Pesticides	Tech.	reserved[3]	Ambrosi et al., 000006666 Desmoras et al., 000006770	-
	(3) Effects of Pesticides on Microbes	Tech.	reserved[3]	Ambrosi et al., 00006667	-
163.62-8(g)	Activated Sludge Metabolism	Tech.	reserved[3]	-	-

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ This data requirement has only partially been fulfilled. The guidelines require that studies be conducted using two temperatures and two concentrations. Therefore, an additional hydrolysis study using a concentration lower than 1.5 ppm and at a temperature other than 20° is needed to assess the fate of phosalone in the water.

2/ Ambrosi et al., 000006409
Ambrosi et al., 000006664
Ambrosi et al., 000006666
Ambrosi et al., 005008305
Ambrosi et al., 005009356
Desmoras et al., 000006770

3/ The requirement for the submission of these data is currently being reserved, pending the review and modification of the testing protocols.

Table A: Phosalone
Generic Data Requirements: Environmental Fate (See Chapter V)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.62-9	Leaching	Tech. or Radiolabeled Analytical Gr.	partially[1/] [2/]	Ambrosi et al., 000006663	yes/12 mo.
163.62-9(c)	Volatility	Tech. Grade	reserved[3/]	-	—
163.62-9(d)	Adsorption/Desorption	Tech. or Radiolabeled Analytical Gr.	no[1/]	-	yes/12 mo.
163.62-10(b)	Terrestrial Field Dissipation:				
	(1) Field & Vegetable Crops	A representive formulated product	no	-	yes/26 mo.
	(2) Tree Fruit & Nut Crop Uses	A representive formulated product	no	-	yes/26 mo.
163.62-10(f)	Combination and Tank Mix Field Dissipation	-	no[4/]	-	4/

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

[1/] For terrestial noncrop users, orchard crop uses, the mobility of the test substance and its degradates in soil shall be assessed either by soil thin-layer chromatography, soil column, or batch equilibrium (absorption/desorption) procedures.

[2/] The rapid leaching study of parent material (phosalone) is valid, but the aged portion of the study is incomplete. (Please refer to Chapter V for a detailed discussion). Therefore, data are still required.

[3/] The vapor pressure is not known. When this data gap has been filled, an assessment can be made concerning the need for a volitilization study.

[4/] Not applicable in single active ingredient standards.

Table A: Phosalone
Generic Data Requirements: Environmental Fate (See Chapter V)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.62-10(g)	Long Term Field Dissipation Study	-	reserved1/	-	-
163.62-11(b)	Accumulation in Rotational Crops	Radiolabeled Analytical Gr. Followed by Formulation	partially2/	Ambrosi et al., 000006664	yes/26 mo.
163.62-11(d)	Fish Accumulation	Tech. or Radiolabeled Analytical Gr.	partially3/	Barrows, M.E., 000006109	yes/26 mo.
163.62-12	Reentry	A Representative Formulated Product	partially4/	Knaak et al., 005003635 Leffingwell et al., 005007744 Leffingwell et al., 005007745 Popendorf et al., 005005243 Winterlin et al., 005001343	4/
163.62-13	Disposal & Storage	Tech. and All Formulated Products	reserved5/	-	-

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ The requirement for the submission of these data is currently being reserved pending the receipt and evaluation of data on terrestial field dissipation. Consequently the absence of acceptable data does not constitute a data gap.

2/ Additional data from field studies are needed to identify residues accumulated by radishes, beans, potatoes, and wheat planted as rotational crops in phosalone-treated fields. In addition, all studies specified in Section 163.62-11(b) are needed for all other crops that may be planted in rotation with phosalone-treated crops. However, this crop rotation restriction may be removed as discussed in Chapter V.

3/ An additional study, using a flow-through system and identifying radio-labeled residues, is needed to satisfy data requirements in Section 163.62-11(d).

4/ Until the Guidelines and the reentry interval review is complete, the Agency intends to maintain the 24 hour reentry interval as an interim measure. If the registrant wishes to appeal, interval data may be submitted to the Agency to support a change. Please see Chapter V for a discussion.

5/ Guidelines for this Section have not been completed, consequently the absence of acceptable data does not constitute a data gap.

Table A: Phosalone
Generic Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.81-1	Acute Oral Toxicity	Each Product or Substantially Similar Product	yes	Dubost et al., 000006643 Fournel et al., 000006716 Pasquet et al., 005007746 Rivett and Davies, 000006697	no
163.81-2	Acute Dermal Toxicity	Ea. Prod. or Substan. Sim. Prod.	yes	Dubost et al., 000006643 Pasquet, 005007746	no
163.81-3	Acute Inhalation Toxicity	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/6 mo.
163.81-4	Primary Eye Irritation	Ea. Prod. or Substan. Sim. Prod.	no[1/]	-	yes/6 mo.
163.81-5	Primary Dermal Irritation	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/6 mo.
163.81-6	Dermal Sensitization	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/6 mo.
163.81-7	Acute Delayed Neurotoxicity	Tech. Grade of A.I.	no[2/]	-	yes/12 mo.
163.82-1	Subchronic Oral Toxicity	Tech. Grade of A.I.	yes	Donoso et al., 000006203 Fournel et al., 000006684 Jones et al., 000006205 Noel et al., 000006111 Woodward et al. 000006202	no
163.82-2	Subchronic 21-Day Dermal	Tech. Grade of A.I.	no	-	yes/12 mo.

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ There are data available for the EC formulation. The registrant may use this study (Horn et al., 1965, MRID 000006690) to fulfill this requirement. However, this places the manufacturing-use product in Toxicity Category I. In this event the Agency would require changes in the label, including a statement specifying the use of protective clothing.

2/ Data are required, because phosalone caused cholinesterase depression.

Table A: Phosalone

Generic Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.82-5	Subchronic Neurotoxicity	Tech. Grade of A.I.	yes	Woodward et al., 000006695	no
163.83-1	Chronic Feeding Toxicity	Tech. Grade of A.I.	yes	Woodward et al. 000006202	no
163.83-2	Oncogenicity	Tech. Grade of A.I.	yes	Rhone-Poulenc, Inc. GS0027021 Woodard et al., 000006202	no
163.83-3	Teratogenicity	Tech. Grade of A.I.	yes	Khera et al., 005008254 Pasquet and Buisson, 000006110	no
163.83-4	Reproduction	Tech. Grade of A.I.	yes	Benazet and Cartier, GS0027020 Collins and Ings, 00006977 Desmoras et al., 000006715 Jones et al., 00006204 Khera et al., 05008254 Pasquet and Buisson, 00006110	no
163.84-2 through-4	Mutagenicity	Tech. Grade of A.I.	yes	Benazet and Cartier GS0027020 Collins & Ings, 000006977 Desmoras et al., 000006715 Goldenthal et al., GS0027019 Jones et al., 000006204 Khera et al., 005008254 Pasquet and Buisson, 000006110 Rhone-Poulenc, Inc., GS0027021 Woodard et al. 000006202	no
163.85-1	Metabolism and Pharmacodynamics	Analytically Pure Radioactive Grade	yes	Collins and Ings, 000006977 Craine, 000006972, 000006973, and 000006975 Desmoras et al. 000006715 Fournel et al., 000006716 Pasquet et al., 005007746	no

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirement

Table A: Phosalone
Generic Data Requirements: Residue Chemistry (See Chapter VII)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
-	Metabolism in Plants	1/	yes	2/	no
-	Metabolism in Animals	1/	yes	Desmoras et al., 000006715 Craine, E.M., 000006974	no
-	Analytical Methods	1/	yes	3/	no
-	Residue Data: Crops	1/	yes	4/	no
-	Residue Data: Processed Crops	1/	yes	5/	no
-	Residue Data: Milk & Meat	1/	yes	6/	no
-	Storage Stability	1/	yes	Desmoras et al., 000006968 Klisenko and Pis'mennaya, 005014548 Laurent et al., 000006698 Rhodia, Inc., 000006113	no

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ Residue of Active Ingredient and its Metabolites Which may be of Toxicological Concern.

2/

Ambrosi et al.	000006125
Desmoras et al.	000006791
Desmoras et al.	000006386
FAO Working Party	005013895
Kovaleva, E.S.	005014688
Nalbanyan, R.A.	005016356
Societe des Usines Chimiques Rhone - Poulenc	000006675
Winterlin et al.	005009309

3/ Desmoras, J.	005016979
Guardigli, A.	000006383
Guardigli, A.	000006703
Guardigli, A.	000006129
Guardigli, A.	000006762
Guardigli, A.	000006105
Guardigli, A.	GS0027010
Guardigli and Melkesian	000006083
Guardigli et al.	005008180
Guardigli et al.	000006678
Laurent et al.	000006700
Societe des Usines Chimiques Rhone-Poulenc	000006701

4/ Almond nutmeats and almond hulls

Guardigli, A.	000006358

Brazil nuts, bush nuts, butternuts, cashews, chestnuts, filberts, hazelnuts, hickery nuts, macadamia nuts, pecans and walnuts (except almonds)

Residue data were submitted for pecans and walnuts under the provision in CFR 40, 180.34 f. i.e. "It may be possible to make a reliable estimate of negligible residues of pesticide chemicals to be expected on each commodity in a designated grouping on the basis of data on a representative number of commodities listed in the following designated groups." Accordingly the submitted data for pecans and walnuts are to be extended to the other nutcrops mentioned above.

Pecans

Guardigli, et al.	000006511

Walnuts

Guardigli, et al.	000006511

Apples

Desmoras et al.	000006707
Guardigli, A.	000006388
Guardigli, A.	000006783
Guardigli, A.	000006711
Guardigli, A.	000006084
Rhodia, Inc.	000006712

Pears

Guardigli, A.,	000006714
Guardigli, A.	000006392

Grapes

Desmoras et al.	000006707
Guardigli, A.	000006390
Guardigli, A.	000006713
Guardigli, et al.	000006480
Laurent et al.	000006708

Citrus Fruit

Guardigli, A.	GS0027014
Guardigli, A.	GS0027015
Guardigli, A.	GS0027016

Artichokes

Henckler, P.	000006964
Societe des Usines Chiniques Rhone-Poulenc	GS0027009

Potatoes

Guardigli, A.	000006395
Guardigli, et al.	000006576

Apricots

Henckler et al.	000006483
US EPA	GS0027006

Cherries

Guardigli, A.	000006389
Henckler et al.	000006484
US EPA	GS0027006

Nectarines	
Henckler et al.	000006485
US EPA	GS0027006
Peaches	
Guardigli, A.	000006391
Henckler et al.	000006486
Rhodia, Inc., Chipman Division	GS0027025
Plums (fresh prunes)	
Rhodia, Inc., Chipman Division	GS0027025
Henckler et al.	000006487
Guardigli, A.	000006769
5/ Dried Raisins	
Guardigli, et al.	000006480
Dried Grape Pomace	
Dennis, S.	000006069
Dried Apple Pomace	
Guardigli, A.	000006068
Rhodia, Inc.	000006357
Dried Citrus Pulp	
Guardiglia, A.	GS0027016
Dried Prunes	
Guardigli, A.	000006769
Henckler, et al.	000006487

Dried tea

Desmoras, et al.	000006209
Rhodia, Inc.	000006210
Crouch, R.V.	000006735

6/ Meat, milk, poultry and eggs.

Collins et al.	000006978
Craine, E.M.	000006972
Craine, E.M.	000006973
Craine, E.M.	000006974
Craine, E.M.	000006975
Guardigli, A.	000006971
Posner, S.	000006761
Posner, S.	000006792
Rhodia, Inc.	000006120
Rhodia, Inc.	000006123
Rhodia, Inc.	000006717
Totman et al.	000006073
Totman et al.	000006071

Table A: Phosalone
Generic Data Requirements: Ecological Effects (See Chapter VIII)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.71-1	Avian Single-Dose Oral LD_{50}	Tech.	no	—	yes/11 mo.
163.71-2	Avian Dietary LC_{50}	Tech.	no	—	yes/11 mo.
163.71-3	Mammalian Acute Toxicity	—	reserved1/	—	1/
163.71-4	Avian Reproduction	—	reserved1/	—	1/
163.71-5	Simulated and Actual Field Testing for Mammals & Birds	—	reserved1/	—	1/
163.72-1	Fish Acute LC_{50}	Tech.	no	—	yes/11 mo.
163.72-2	Acute Toxicity to Aquatic Invertebrates	Tech.	no	—	yes/11 mo.
163.72-3	Acute Toxicity to Estuarine & Marine Organisms	—	reserved1/	—	1/
163.72-4	Embryolarvae & Life-cycle Studies of Fish & Aquatic Invertebrates	—	reserved1/	—	1/
163.72-5	Aquatic Organism Toxicity & Residue Studies	—	reserved1/	—	1/
163.72-6	Simulated or Actual Field Testing for Aquatic Organisms	—	reserved1/	—	1/

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ The requirement for the submission of the data is currently reserved, pending the results of the outstanding data.

Table A: Phosalone
Generic Data Requirements: Ecological Effects (See Chapter VIII)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.122-1	Seed Germination	Technical	no	-	yes/26 mo.
163.122-1	Vegetative Vigor	Technical	partially1/	1/	yes/26 mo.
163.122-2	Aquatic Macrophytes	Technical	no	-	yes/26 mo.
163.122-2	Algae	Technical	no	-	yes/26 mo.

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ The data requirement has been partially filled by the following studies in aggregate:

Ciarletta et al.	000014256
Delay, D.L.	000006528
Delay, D.L.	000006534
Delay, D.L.	000006569
Eckenrode et al.	005015711
Ishitani et al.	005006342
Knobel, H. and Rock, G.	000006938
Knobel, H. and Rock, G.	000006939
Lillie, D.T.	000006430
Lillie, D.T. and Carman, G.	000006747
Lillie, D.T. and Carman, G.	000006748
Preiser, F.A. and Taschenberg, E.F.	000006479
Rhodia, Incorporated	000006733
Smyth et al.	000006243
Smyth, E.P. and Hoyt, S.	000006639
Smyth, E.P. and Jones, S.C.	000006283
Spencer, W.T. and Hofmaster, R.N.	000006738
Szabo, J. and Wells, A.	000006592
Szabo, J. and Sleesman, J.P.	000006593
Wang, D.	000006114
Wang, D.	000006115
Wang, D.	000006289
Wang, D.	000006477
Wang, D.	000006145

To complete the vegetative vigor data requirement, data are needed on the effects of phosalone on monocot plants.

Table B: Phosalone

Product Specific Manufacturing-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.61-3	Product Identity & Disclosure of Ingredients	Each Product	yes	-	yes[1]
163.61-4	Description of Manufacturing Process	Each Product	yes	-	yes[1]
163.61-5	Discussion on Formation of Unintentional Ingredients	Each Product	yes	-	yes[1]
163.61-6	Declaration & Certification of Ingredients Limits	Each Product	yes	-	yes[1]
163.61-7	Product Analytical Methods & Data	Each Product	yes	2/	no

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ This requirement must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. This requirement must be filled at the time of registration. However, this requirement has been fulfilled for current registrations. Please refer to Chapter IV for a discussion of the data.

2/ Brun et al., 005005128
Guardigli, A., 000006640
Guardigli, A., 000006170
Henckler, R., 000006107
Laurent, M., 000006645
Maharova et al., 0050011351
Societe des Usines Chemiques Rhone - Poulenc, GS0027009
Societe des Usines Chemiques Rhone - Poulenc, 000006398
Societe des Usines Chemiques Rhone - Poulenc, 000006943

Table B: Phosalone

Product Specific Manufacturing-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.61-8(c)(1)	Color	Technical Grade of Active Ingredient	yes	—	yes1/
163.61-8(c)(2)	Odor	Tech. Grade of A.I.	yes	—	yes1/
163.61-8(c)(3)	Melting Point	Tech. Grade of A.I.	yes	—	yes1/
163.61-8(c)(4)	Solubility	Tech. Grade of A.I.	partially3/	—	yes2/
163.61-8(c)(5)	Stability	Tech. Grade of A.I.	yes	—	yes1/
163.61-8(c)(6)	Octanol/Water Partition Coefficient	Tech. Grade of A.I.	yes	—	yes1/
163.61-8(c)(7)	Physical State	Tech. Grade of A.I.	yes	—	yes1/
163.61-8(c)(8)	Specific Gravity	Tech. Grade of A.I.	no	—	yes1/
163.61-8(c)(9)	Boiling Point	Tech. Grade of A.I.	4/	—	no
163.61-8(c)(10)	Vapor Pressure	Tech. Grade of A.I.	no	—	yes2/
163.61-8(c)(11)	pH	Tech. Grade of A.I.	5/	—	no

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirements have been partially or completely fulfilled for some products, no references are given. These requirements must be filled at the time of registration. However, this requirement has been fulfilled for current registrations. Please refer to Chapter IV for a discussion.

2/ This requirement must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. This requirement must be filled at the time of registration or reregistration.

3/ Since phosalone is practically insoluble in water, the solubility for other solvents i.e. benzene, dioxane, methylene chloride, methanol, ethanol, choroform, xylene etc. in terms of g/100ml of solvent at 20°C or in ppm should be reported to fulfill this requirement for current registrations.

4/ This is not needed, because phosalone is a solid.

5/ Phosalone is practically insoluble in water (1.7 ppm at 20°C); therefore, no pH data are required.

Table B: Phosalone

Product Specific Manufacturing-Use Product Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.61-8(c)(12)	Storage Stability	Each Manufacturing-Use Product	yes	—	yes[1]
163.61-8(c)(13)	Flammability	Each Manufacturing - Use Product	no	—	yes[2]
163.61-8(c)(14)	Oxidizing/Reducing Action	Each Manufacturing-Use Product	yes	—	yes[1]
163.61-8(c)(15)	Explosiveness	Each Manufacturing-Use Product	no	—	yes[2]
163.61-8(c)(16)	Miscibility	Each Manufacturing-Use Product	no	—	yes[2]
163.61-8(c)(17)	Viscosity Coefficient	Each Manufacturing-Use Product	no	—	yes[2]
163.61-8(c)(18)	Corrosiveness	Each Manufacturing-Use Product	no	—	yes[2]

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ This requirement must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. This requirement must be filled at the time or registration. However, this requirement has been fulfilled for current registrations. Please refer to Chapter IV for a discussion of the data.

2/ This requirement must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. This requirement must be filled at the time or registration or reregistration.

Table C: Phosalone
Product Specific End-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.61-3	Product Identity & Disclosure of Ingredients	Each Product	yes	—	yes[1/]
163.61-4	Description of Manufacturing Process	Each Product	no	—	yes[2/]
163.61-5	Discussion on Formation of Unintentional Ingredients	Each Product	yes	—	yes[1/]
163.61-6	Declaration & Certification of Ingredients Limits	Each Product	yes	—	yes[1/]
163.61-7	Product Analytical Methods & Data	Each Product	yes	3/	no

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ This requirement must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. These requirement must be filled at the time of registration. However, this requirement has been fulfilled for current registrations. Please refer to Chapter IV for a discussion of the data.

2/ This requirement must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. This requirement must be filled at the time or registration or reregistration.

3/ Brun et al., 05005128
Guardigli, A., 00006640
Guardigli, A., 00006170
Henckler, P., 00006107
Laurent, M. 00006645
Makarova et al., 05011351
Societe des Usines Chemiques Rhone-Poulenc, 00006398
Societe des Usines Chemiques Rhone-Poulenc, GS0027009,
Societe des Usines Chemiques Rhone-Poulenc, 00006943

Table C: Phosalone
Product Specific End-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.61-8(c)(1)	Color	Each Product	no	—	yes[1/]
163.61-8(c)(2)	Odor	Each Product	no	—	yes[1/]
163.61-8(c)(7)	Physical State	Each Product	no	—	yes[1/]
163.61-8(c)(8)	Specific Gravity	Each Product	no	—	yes[1/]
163.61-8(c)(11)	pH	Each Product	no	-	yes[1/]
163.61-8(c)(12)	Storage Stability	Each Product	no	-	yes[1/]
163.61-8(c)(13)	Flammability	Each Product	no	-	yes[1/]
163.61-8(c)(14)	Oxidizing/Reducing Action	Each Product	no	-	yes[1/]
163.61-8(c)(15)	Explosiveness	Each Product	no	-	yes[1/]
163.61-8(c)(16)	Miscibility	Each Product	no	-	yes[1/]
163.61-8(c)(17)	Viscosity Coefficient	Each Product	no	-	yes[1/]
163.61-8(c)(18)	Corrosiveness	Each Product	no	-	yes[1/]

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

[1/] This requirement must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirements have been partially or completely fulfilled for some products, no references are given. This requirement must be filled at the time of registration or reregistration.

Table C: Phosalone (Emulsifiable Concentrate)
Product Specific End-Use Product Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.81-1	Acute Oral Toxicity	Each Product or Substantially Similar Product	yes	Rivett and Davies, 000006697 Scott and Beliles, 000006688 US EPA, GS0027004 US EPA, GS0027006	no
163.81-2	Acute Dermal Toxicity	Ea. Prod. or Substan. Sim. Prod.	yes	Horn et al., 000006689	no
163.81-3	Acute Inhalation Toxicity	Ea. Prod. or Substan. Sim. Prod.	yes	Beliles, 000006981	no
163.81-4	Primary Eye Irritation	Ea. Prod. or Substan. Sim. Prod.	yes	Horn et al., 000006690	no
163.81-5	Primary Dermal Irritation	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/6 mo.
163.81-6	Dermal Sensitization	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/6 mo.

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

Table C: Phosalone (Wettable Powder)
Product Specific End-Use Product Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.81-1	Acute Oral Toxicity	Each Product or Substantially Similar Product	yes	US EPA, GS0027005 US EPA, GS0027003	no
163.81-2	Acute Dermal Toxicity	Ea. Prod. or Substan. Sim. Prod.	yes[1]	Horn et al., 000006689	no
163.81-3	Acute Inhalation Toxicity	Ea. Prod. or Substan. Sim. Prod.	yes[1]	Beliles, 000006981	no
163.81-4	Primary Eye Irritation	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/6 mo.
163.81-5	Primary Dermal Irritation	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/6 mo.
163.81-6	Dermal Sensitization	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/6 mo.

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

[1] The data for the EC formulation will fulfill this data requirement for the WP formulation.

CHAPTER IV: PRODUCT CHEMISTRY

A. Chemistry Profile
B. Data Gaps

A. Chemistry Profile

The data concerning product chemistry, which fulfill or partially fulfill Agency guideline requirements are discussed below. They are grouped by topic, corresponding to specific sections in the guidelines.

1. Chemical Identity

Phosalone is the accepted common name for O,O-diethyl S-[(6-chloro-2-oxobenzoxazolin-3-yl-)methyl] phosphorodithioate as determined by the American National Standards Institute (1967). Trade names for phosalone include Zolone®, Rubitox®, RP-11974 and NPH-1091.

The molecular weight of phosalone is 367.82. The chemical formula is $C_{12}H_{15}PS_2NO_4Cl$ (Sauli, M., 1975, MRID 005017962).

No additional data are required with regard to phosalone's chemical identity for current manufacturing-use and end-use product registrations.

2. Manufacturing Process

Rhodia, Inc., Agricultural Division, Monmouth Junction, New Jersey, is the sole registrant for phosalone in the United States. It is manufactured by Rhone-Poulenc, Inc. in Paris, France.

Sauli (1975, MRID 005017962) describes a French patent in which phosalone is synthesized in a single phase condensation process of an alkali salt or an ammonium salt of 0,0-diethyldithiophosphoric acid, formaldehyde and 6-chlorobenzoxazolone in the presence of methane sulphonic acid.

A complete description of the manufacturing process has been supplied to the Agency. Details of this process, however, are considered by the Agency to be trade secret information and will not be provided within this standard.

No further information is required for the current manufacturing-use product. No data are available for the end-use products.

3. Formation Of Unintentional Ingredients

Detailed information is available concerning unintentional impurities which may be present in technical phosalone. Like the manufacturing process, this information is considered trade secret and will not be provided within this standard.

The data which have been submitted fulfill this data requirement for the current manufacturing-use and end-use product registrations.

4. Percentage Of Active Ingredient in Pesticide Products

A confidential statement of formula by Rhodia, Inc. reveals that technical phosalone contains 94 percent active ingredient. The remaining six percent consists of manufacturing impurities.

Phosalone is sold as an EC containing 34.4 percent active ingredient (three pounds active ingredient per gallon) and as a WP containing 25 percent active ingredient.

The information concerning the remaining ingredients for the technical and formulated products, as well as the nature of these formulations, is considered trade secret and, hence, will not be described within this standard.

No additional data are required for the current manufacturing-use and end-use product registrations.

5. Product Analytical Methods and Data

Analytical methods for the identification and quantification of phosalone in the technical material and formulated end-use products have been submitted. Methods for the analysis of unintentional impurities have also been submitted and are considered to be adequate.

The methods consist of Gas-Liquid Chromatography with electron capture detection and various Thin Layer Chromatographic procedures (Guardigli, A., 1968, MRID 000006170; Guardigli, A., 1969, MRID 000006640; Henckler, P., 1973, MRID 000006107; Societe des Usines Rhone-Poulenc, Inc., 1973, GS0027009; Societe des Usines Chimiques Rhone-Poulenc, 1966, MRID 000006398).

Infrared (IR) and Ultraviolet (UV) spectra for phosalone have also been submitted (Societe des Unines Chemiques Rhone-Poulenc, 19??, MRID 000006943). A colorimetric method including IR and UV spectrometry is detailed in Laurent (1964, MRID 000006645.) An alternate method for phosalone identification consists of a procedure combining thin-layer chromatography and fluoresence spectroscopy (Brun et al., 1973, MRID 005005128). Another method for the determination of phosalone entails the application of iodometric titration (Makarova et al., 1972, MRID 005011351).

These various analytical methods have been reviewed by the Agency and have been found to fulfill all data requirements with respect to analytical methodology for current manufacturing-use and end-use product registrations.

6. Physical and Chemical Properties

The data which are available concerning these properties for manufacturing-use phosalone are described below. Unless otherwise indicated these data requirements are considered fulfilled for the current manufacturing-use products. There are no data available to describe the formulated products.

a. Color

The color is white (Rhodia, Inc., 19??, MRID 000006651).

b. Odor

The odor is reminiscent of garlic (Rhone-Poulenc, Inc., 1966, MRID 000006172).

c. Melting Point

The melting point is 45-47°C (Rhodia, Inc., 19??, MRID 000006651).

d. Solubility

At 25°C (Rhodia, Inc., 19??, MRID 000006113) phosalone is practically insoluble in water, cyclohexane and petroleum ether. At 20°C (Laurent et al., 1975, MRID 000006067) phosalone has low water solubility, approximately 1.7 ppm . Freed et al. (1979, MRID 005018633) reported the solubility as 2.15 ppm. It is soluble in benzene, dioxane, ethanol, methylene chloride, methanol, acetone, chloroform, acetonitrile, xylene and isophorone.

The proposed registration guidelines state in Section 163.61-8(4) that solubility data are required in g/100 ml of solvent at 20°C (68°F) or in terms such as ppm (mg/kg).

Accordingly, the above solubility data, with the exception of solubility in water, are inadequate and further data are required.

e. Stability

Technical phosalone is an organophosphorus compound relatively stable to heat (up to 100°C) and acid media. Hydrolysis occurs under alkaline conditions, but more slowly than for many other organophosphorus insecticides (Desmoras et al., 19??, MRID 000006968; Rhodia, Inc., 19??, MRID 000006113.)

The rate of decomposition is a function of exposure to UV light and is as follows:

The constant of reaction rate under UV light is 0.0081/sec and the half life is 86 minutes (Klisenko, M.A. and Pis'mennaya, M.V., 1973, MRID 005014548).

f. Octanol/Water Partition Coefficient

The logarithm of the octanol/water partition coefficient at 20°C is 4.30 (Freed et al., 1979, MRID 005018633).

g. Physical State

The physical state is crystalline (USA Standards Institute, 1967, MRID 000006668).

h. Vapor Pressure

The vapor pressure of phosalone at 20°C is negligible; however, specific figures are not available. The phosalone concentration of a saturated atmosphere is <0.01 mg/m^3 (Desmoras et al., 19??, MRID 000006968).

The registrant is required to supply the exact figures for vapor pressure in torr or mm Hg. Thus, the data are required.

i. pH

Since phosalone is practically insoluble in water, no pH data are required.

j. Storage Stability

Results of stability studies on a technical lot of phosalone stored for six months and also for two years show that phosalone is very stable under normal laboratory conditions for a period of two years without risk of notable degradation (Laurent et al., 1965, MRID 000006698). The stability of bulk or formulated products is excellent. No appreciable loss in activity was observed in either normal temperature storage trials or from a month of accelerated storage at 50° (Rhodia, Inc., 19??, MRID 000006113).

k. Oxidizing or Reducing Action

Under acidic conditions, no significant degradation of phosalone takes place. Under alkaline conditions, phosalone is not stable and at 20°C exhibits a half life of about nine days (Laurent et al., 1975, MRID 000006067).

B. Data Gaps

Please refer to the data charts in Chapter III for the requirements, which need to be fulfilled.

CHAPTER V: ENVIRONMENTAL FATE

A. Use Summary
B. Environmental Fate Profile
C. Exposure Profile
D. Data Gaps

A. Use Summary

Phosalone is an insecticide/miticide federally registered for commercial use to control a variety of insect and mite pests on fruit, nut, vegetable, and ornamental crops. Approximately 80 percent of phosalone applications are made on pecans in the southeastern and southwestern states. Other major application sites are for apples in the eastern, western and north central states, and for grapes in California and Arizona.

Phosalone is formulated into a 25 percent active ingredient wettable powder formulation used predominantly on apples and grapes, and a 34.4 percent active ingredient emulsifiable concentrate formulation used predominantly on pecans, apples, and grapes. Application rates for these crops range from 0.25-1.0 pounds active ingredient per 100 gallons of water (1.0-4.0 pounds active ingredient per acre.) Both formulations are mixed with water and applied as foliar applications with aircraft and ground equipment, including air-blast sprayers, hydraulic sprayers fitted with a single wand (gun) or boom, and others. The type of equipment is determined by the site and equipment availability.

Approximately 1.5-2 million pounds active ingredient are imported annually from France. No phosalone production is reported in the United States.[1/]

B. Environmental Fate Profile

The environmetal fate studies which fulfill or partially fulfill the data requirements are discussed below. They are grouped by topic to correspond to specific sections in the Guidelines.

1. Hydrolysis

Phosalone is stable over a pH range of 5-7, but is hydrolyzed at pH 9 with a half-life of nine days. In a hydrolysis study at pH 9, more than 15 distinct degradation products were found after four weeks. No single degradation product exceeded 10 percent of the applied phosalone. Only four degradation products were identified: phosalone-oxon, 6-chloro-benzoxazolone, 3-amino-7-chloro-2-phenoxazone, and its precursor, 2-amino-5-chlorophenol (Laurent et al., 1975, MRID 000006067).

This study, however, only partially fulfills the hydrolysis data requirement. The guidelines require two temperatures and two concentrations to fulfill this data requirement. Therefore, a hydrolysis study using a concentration lower than 1.5 ppm and at a temperature other than 20° C is needed to fully assess the fate of phosalone in the water.

1/ No confidential business information has been used to arrive at this EPA estimate of production volume.

2. Photolysis

Phosalone degrades in irradiated water and soil. The data indicate half-lives of 15-20 minutes and about one day, respectively, for water and soil. In irradiated water, approximately 20 degradation products have been isolated, with hydroxyl-phosalone being the major degradation product. Carbon dioxide, 6-chlorobenzoxazolone, and phosalone-oxon, were identified as minor degradation products. About 97 percent of the applied phosalone degraded in nonsterile irradiated soil after one month. Only 30 percent degraded in sterile clay loam soil under light, and 15 percent degraded in the dark. Dechlorinated phosalone and the oxygen analogue were the major degradation products found in irradiated soil, and carbon dioxide was a minor product of photolysis (Ambrosi et al., 1974, MRID 000006409; Ambrosi et al., 1977, MRID 000006666; Laurent et al., 1977, MRID 000006665).

These studies fulfill the data requirement pertaining to the photodegradation of phosalone.

3. Aerobic Soil Metabolism

Phosalone half-lives in soil metabolism studies ranged from less than one day (type of soil unidentified) to seven days (Beauce soil). Identified metabolites were phosalone-oxon, 6-chlorobenzoxazolone, diethyldithiophosphoric acid, diethylthionophosphoric acid, bis-0,0- diethylthionophosphoryl disulfide, 0,0-diethylthiophosphonyl disulfate, 0,0-diethylphosphonyl disulfate, and 3-amino-7-chloro-2-phenoxazone. The following degradation products were also rapidly degraded in soil: dechlorinated phosalone, phosalone-oxon, 6-chlorobenzoxazolone, and 3-amino-7-chloro-2-phenoxazone. Neither identified nor unidentified polar and nonpolar extractable metabolites accumulated in soil. Unextractable radiolabeled residues rapidly accumulated to 70-90 percent of the applied ^{14}C phosalone under aerobic and flooded (semi-aerobic) conditions. The unextractable residues were associated primarily with the fulvic acid fraction. Under aerobic conditions, slightly less than 10 percent of the applied ^{14}C phosalone was lost as carbon dioxide within one month (Ambrosi et al., 1974, MRID 000006409; Ambrosi et al., 1977, MRID 00006664; Ambrosi et al., 1977, MRID 000006666; Ambrosi et al., 1977, MRID 005009356; Ambrosi et al., 1978, MRID 005008305; Desmoras et al., 1975, MRID 000006770.

These studies meet guideline requirements. However, the unextractable residues interfere with development of a metabolic pathway. For example, before degradates are formed, the parent, and possibly some metabolites, are unextractable. Usually from 60 to 90 percent of total phosalone is unextractable, but is present in the soil and taken up by rotational crops.

These studies adequately characterize the aerobic soil metabolism of phosalone and fulfill all data requirements.

4. Microbial Metabolism: Effects of Microbes on Pesticides

Microbial metabolism appears to be the primary mechanism responsible for phosalone degradation in soil, accounting for 60 to 86 percent of its degradation during a two or four week period. The organisms responsible for the degradation, however, have not been identified (Ambrosi et al., 1977, MRID 000006666 and Desmoras et al., 1975, MRID 000006770).

The above data partially fulfill Agency requirements by demonstrating the role of microbial metabolism on phosalone degradation. No data are, however, available on the identity of the organisms responsible for phosalone degradation.

Despite the noted deficiency, the requirement for the submission of the additional data is currently being reserved. The absence of acceptable data within this topic does, therefore, not constitute a data gap.

5. Microbial Metabolism: Effects of Pesticides on Microbes

Limited data suggest that phosalone has variable effects on microbes. The degradation of radiolabeled cytosine, glucose, glycine, guanine, phenylalanine, and urea in soil was only temporarily inhibited by phosalone treatment at 10 and 100 ppm. At 1 ppm phosalone had no effect on soil dehydrogenase activity over an eight day period, whereas at 10 ppm activity was inhibited by 20 percent. Soybean nodule formation by Rhizobium japonicum was not inhibited by phosalone at $\leq$ 100 ppm. Phosalone treatment of soil at 1 and 10 ppm enhanced oxygen consumption over a six hour period. Preliminary data also indicate that nitrification and the growth of bacteria may be slightly inhibited by phosalone (Ambrosi et al., 1976, MRID 000006667).

These data are not sufficient to satisfy this data requirement. Further information on the effects of phosalone on important soil microbial functions such as oxygen consumption, nitrification, denitrification, nitrogen fixation, and microbial degradation of starch and protein is needed. This requirement, like the preceding, is currently being reserved. Consequently, the absence of acceptable data within this topic does not constitute a data gap.

6. Leaching

Phosalone (^{14}C radiolabeled) did not leach from columns of unaged soils loamy sand, sandy loam, clay loam, and silt loam (Ambrosi et al., 1975, MRID 000006663). The rapid leaching study of parent material (phosalone) is valid, but the aged portion of the study is incomplete. For example, the column was not leached long enough (only three days) and the identification of metabolites was not reported. Also, the method for identification of metabolites was not mentioned. The aged soil should be leached for more than 30 days and metabolites determined. These deficiencies consistute a data gap in the (aged) leaching study.

7. Volatility

The vapor pressure of phosalone is not known. When this data gap is filled, an assessment can be made concerning the need for a volatilization study.

8. Accumulation in Rotational Crops

The current use pattern indicates that phosalone is used to treat potatoes and artichokes as field crops. Artichokes are perennials and are not rotated with any other crop; however potatoes are rotated with several other field crops.

Data from rotational crop studies under greenhouse conditions indicate that phosalone and/or its metabolites can accumulate in radishes, beans, potatoes, and wheat planted 1.5 to 5.5 months after soil treatment with phosalone at 3 ppm (Ambrosi et al., 1977, MRID 000006664).

Due to the appearance of phosalone residues in greenhouse crops, field studies are required to determine if residues would occur under actual use conditions.

In addition, all studies specified in Section 163.62-11(b) are needed for all other crops identified by the registrant that may be planted in rotation with phosalone-treated crops.

If the registrant does not wish to have a rotational crop restriction on a phosalone product, one of the following must be done:

a. Supply environmental fate data supporting a rotation interval which does not result in a pesticide residue in the rotated crops; or

b. Obtain a tolerance for the nontarget crop (46 FR 3018); or

c. Obtain an exemption from a tolerance for the nontarget crop.

In the interim a label amendment restricting phosalone use in crop rotation programs will be required. (See Chapter II for for a more detailed discussion).

9. Fish Accumulation

Maximum bioaccumulation factors for catfish, crayfish, bluegill, and rainbow trout were about 31, 21, 16, and 16, respectively following exposure at <0.3 to 0.99 ug/liter of [^{14}C]phosalone over 28 days in a static system. Residue levels in edible tissues declined to undetectable levels (<3 ppb) between the 28th and 3rd day of exposure. Depuration of residues in nonedible tissues was complete by day seven of the depuration period for all species tested. Therefore, [^{14}C]phosalone appears to exhibit a low bioaccumulation potential in fish (Barrows, M.E., 1975, MRID 000006109).

Two exposure systems are required by the 1978 guidelines. Therefore, an additional study using a flow-through system and identifying radiolabeled residues is needed to satisfy this data requirement.

10. Reentry

Reentry intervals are required to support the registration of all products for which the Agency has determined that a reentry hazard exists for persons reentering treated sites. Phosalone is an acetyl-cholinesterase inhibiting pesticide which may present a hazard to persons reentering treated fields. The parent and phosalone-oxon tend to persist, especially under dry conditions and present a more hazardous reentry situation.

Popendorf et al., (1979, MRID 005005243) found a correlation between the amount of dislodgable phosalone residues in peach orchards and the total dermal doses of workers in the orchard. However, workers exposed to phosalone residue levels up to 7 ug/cm^2 on peaches showed no blood cholinesterase depression. Higher levels would not be expected to occur under actual use conditions.

Several studies presented the results of phosalone residue levels on grapes. In one study, phosalone was applied at three pounds active ingredient per acre twice within a five day period to grapes in California. Levels of dislodgeable foliar phosalone at harvest 87 to 98 days after the last application were approximately 0.075 to 0.45 ug/cm^2 (Knaak et al., 1978 MRID 005003635). Dislodgeable foliar phosalone and phosalone-oxon levels in another study were estimated at <0.1-4.8 and <0.1 to 0.83 ppm after 111-115 days, respectively (Winterlin et al., 1978, MRID 005001343). In a separate field sprayed with phosalone at three pounds active ingredient per acre, dislodgeable foliar phosalone levels were estimated at 0.7 ug/cm^2 68 days after application (Knaak et al., 1978, MRID 005003635).

Two other studies in California showed that hot weather enhances phosalone's dissipation on the surface of grape foliage treated with phosalone 3 EC at 2.1-3 pounds active ingredient per acre. In one study (Leffingwell et al., 1975, MRID 005007745), dislodgeable phosalone, initially at approximately 175 ppm (approximately 4 ug/cm^2), had a half-life about seven days in hot humid weather (up to 114°), and a half-life of approximately 14 days in cooler weather (95 to 105° maximum). In the other study (Leffingwell et al., MRID 005007744), about 25 to 65 percent of the dislodgeable phosalone dissipated within seven to nine days when maximum air temperatures were generally >40° C (104°). When maximum air temperatues dropped to 38° C (100°F), the dissipation rate slowed and phosalone's half-life was >30 days. The temperature effect is probably due to enhanced volatilization and chemical reaction.

In both studies the oxygen analogue accumulated to 2.5 to 6.5 ppm (70 to 180 ng/cm^2) during the first eight days after phosalone application. The accumulation rate slowed thereafter and the level was relatively constant at 6 to 10 ppm (100 to 250 ng/cm^2) 20 to 35 days after application. Neither the decline pattern of phosalone nor the accumulation of phosalone-oxon was affected by variable spray concentrations that ranged from 2.25 pounds active ingredient per acre in 50 gallons of water to three pounds active ingredient per acre in two gallons. However, the initial concentration of dislodgeable phosalone was higher with higher spray concentrations. For example, dislodgeable phosalone levels were about 10 to 16 ug/cm^2 one to two days after application at three pounds active ingredient per acre in twelve gallons, whereas levels were about 3 to 5 ug/cm^2 one day after application at three pounds active ingredient per acre in 50 gallons (Leffingwell et al., 1975, MRID 005007745) or 2.25 pounds active ingredient in 23 to 30 gallons of water per acre (Leffingwell et al., 1974, MRID 005007744).

All these studies show that phosalone and phosalone-oxon residues are present on crop surfaces several weeks after treatment with phosalone. Thus a safe reentry interval must be established to protect persons reentering treated fields from toxic effects of this cholinesterase inhibitor. For each crop, the registrant is required to propose an acceptable reentry interval. This proposed interval may be based on the following:

a. Data on dissipation of foliar residues (decline curve), on human exposure to those residues; and on the inherent toxicity of phosalone;

b. A determination of the time after which no detectable foliar residues occur under appropriate climatic conditions, in the geographical area in which phosalone will be applied.

Phosalone is an organophosporothioate (OP) pesticide. These OP pesticides are among the most toxic pesticides used in American agriculture. They have caused the majority of the reported incidents of field worker poisoning episodes, and most of these have been in California. Phosalone has been implicated as a causative factor in a number of the incidents. In response to these poisoning incidents, reentry intervals for phosalone have been proposed twice by the Occupational Safety and Health Administration of the

Department of Labor and twice by the Environmental Protection Agency (EPA) [38 (83) Federal Register 10715; 38 (125) Federal Register 17211; 39 (48) Federal Register 9457; 39 (92) Federal Register 16888, respectively.] The last proposed reentry interval of 24 hours was established for phosalone in 40 CFR 170. The State of California has established a seven day reentry interval in response to the unusual environmental conditions within that State with the provision that the reentry interval would be waived, if two inches of rain occurred or if the equivalent of two inches of rain were applied to the crop as an overhead spray. Knaaket al. (1980, MRID GS0027027) has proposed that the Reentry Level for phosalone should be 7.0 ug/cm^2.

Guidelines for the establishment of Reentry Intervals will soon be proposed by the EPA. Within those Guidelines it will be proposed that reentry intervals and reentry (residue) levels will be required for the registration of any pesticide that meets certain criteria. One of the criteria is that the pesticide has been implicated in poisoning incident(s). Phosalone meets that criteria. The Agency is currently reviewing the established 24 hour reentry interval for phosalone in the light of current scientific information and the methodology presented in the proposed Guidelines.

Until the Guidelines and the reentry interval review is complete, the Agency intends to maintain the 24 hour reentry interval as an interim measure. If the registrant wishes to appeal, interval data may be submitted to the Agency to support a change.

11. Summary

Although insufficient data are available to form a complete profile of phosalone's environmental fate, the available information suggests that phosalone will hydrolyze at moderately alkaline pH's and will rapidly photodegrade in water. In soil the degradation of phosalone occurs mainly by microbial action, though some degradation results from photolysis. The half-life of phosalone in soil will generally range from less than one day to seven days. The major products of hydrolysis, photolysis, and soil metabolism are phosalone-oxon, dechlorinated phosalone, 6-chlorobenzoxazolone, and 3-amino-7-chloro-2 phenoxazone, all of which are also rapidly degraded in soil. At least 20 unidentified degradation products are formed in minute amounts. The microbial degradation of glucose, amino acids, and urea in soil is only temporarily inhibited by phosalone treatment at concentrations higher than the recommended field dosage rate. The compound does not adversely affect soil dehydrogenase activity. Phosalone and its metabolites will not leach through most types of soils. The potential for accumulation of phosalone and its metabolites in fish is low. However, the identity of the residues taken up by fish is unknown. Although phosalone rapidly dissipates in soil, unidentified residues may accumulate in radishes, beans, potatoes, and wheat planted as rotational crops in treated fields. Although with adequate precautions phosalone can be safely used, proper reentry intervals are necessary to avoid potential hazards.

C. EXPOSURE PROFILE

1. All Formulations

The use of airblast machines and aircraft increases the potential for exposure via spray drift to humans, livestock or wildlife outside the application site. The potential for human exposure via groundwater contamination is low, as studies with several aged and unaged soils (loamy sand, sandy loam, clay loam and silt loam) show that phosalone does not leach. The bioaccumulation potential is also low, with maximum bioaccumulation factors in catfish, crayfish, bluegill, and rainbow trout reported at 31, 21, 16, and 16, respectively.

The mixers and applicators of phosalone formulations have the highest potential for direct exposure, but no quantitative data are available to estimate the degree of such exposure. Dermal and eye exposure from splashing during diluting and mixing operations can result from the use of the emulsifiable concentrate. Respiratory exposure from "puff back" can occur during opening and pouring of the wettable powder formulation.The precautionary statements on the label regarding the use of protective clothing, gloves, and respirators are adequate to ensure the safety of the mixers and applicators.

2. Wettable Powder Formulation

One study was conducted to measure worker exposure to phosalone formulated as a wettable powder following entry into treated fields (Popendorf et al., 1979, MRID 005005243). There was a very good correlation between estimated dermal dose and exposure to specific dislodgeable foliar residues. Dislodgeable foliar phosalone residues, at harvest, ranged from 1,800 ng/cm^2 (22 to 24 days post application) to 7,180 ng/cm^2 (seven to nine days post application). Dislodgeable phosalone-oxon residue levels were one to three percent of the total phosalone applied and ranged from 24 to 190 ng/cm^2, at harvest. Workers harvesting peaches 3 to 24 days after phosalone applications, at four to five pounds active ingredient per acre received estimated average dermal doses of phosalone and its oxygen analogue of 9.8 (7.2 to 13.9) and 0.16 (0.15 to 0.20) mg/hour, respectively. Approximately 98 to 99 percent of the total dose was attributed to dermal rather than respiratory exposure. The estimated respiratory dose of phosalone was approximately 72 ug/hour. The average individual shift in red blood cell cholinesterase depression was eight to nine percent, well within the normal range of daily fluctuations. Worker red blood cell cholinesterase activity was slightly inhibited (a mean of approximately four percent), when compared to an unexposed control population. This is not a toxicologically significant decrease. Also, there were no overt signs of cholinergic effects.

3. Unspecified Formulation

Orange trees in two adjacent fields in California were sprayed with an unspecified formulation of phosalone at six pounds active ingredient per acre in 600 gallons of water (Knaak et al., 1978, MRID 005008190). Half-lives of 13 and 21 dayswere obtained for dislodgeable foliar phosalone at initial levels of 6.4 and 7 ug/cm^2, respectively. Workers pruning trees 14 to 21 days after application were exposed for three days to dislodgeable phosalone and oxygen analogue at 2.6 to 3.6 and 0.2 to 0.5 ug/cm^2, respectively.

Red blood cell cholinesterase activity in exposed workers was not significantly different from unexposed controls. Plasma cholinesterase activity of the workers was significantly lower in both the 14 and 21 day studies. Neither phosalone nor its metabolites were detected in the urine of exposed workers (limits of detectability for phosalone, phosalone oxon and 2-amino-5-chlorophenol were 0.10, 0.10 and 0.16 ppm, respectively).

D. Data Gaps

Several studies are still needed to fulfill the data requirements for the environmental fate of phosalone. These data requirements include hydrolysis, anaerobic soil metabolism, adsorption/desorption, terrestrial field dissipation for field and vegetable crop uses and tree fruit and nut crop uses, accumulation in rotational crops, and fish accumulation.

For labeling requirements regarding crop rotation and reentry intervals, please refer to Chapter II.

CHAPTER VI: TOXICOLOGY

A. Toxicology Profile - Manufacturing-Use Phosalone
B. Toxicology Profile - End-Use Products
C. Toxicology Profile - Oxygen Analogue
D. Hazard Assessment - Manufacturing-Use and End-Use Products
E. Data Gaps - End-Use Products

A. Toxicology Profile - Manufacturing-Use Phosalone

The studies which fulfill or partially fulfill the data requirements for manufacturing-use phosalone are grouped by topics corresponding to the appropriate section, which describes those requirements in the Guidelines.

1. Acute Oral Toxicity

Sufficient data are available to show that phosalone has high acute oral toxicity, which places phosalone in Toxicity Category II (See Table 1). Signs of toxicity included salivation, lacrimation, muscle fasciculations, convulsions, and respiratory disfunction which preceded death. Most deaths occurred within 24 hours of dosing.

Therefore, additional data are not required.

2. Acute Dermal Toxicity

There are sufficient data to demonstrate that the manufacturing-use formulation has a high degree of acute dermal toxicity, which places phosalone in Toxicity Category II. The dermal LD_{50} is 1530 mg/kg in rabbits with a minimum lethal dose of 320 mg/kg (Pasquet et al., 1976, MRID 005007746). Deaths occurred within four days of administration. In a second study acute dermal LD_{50} values for rabbits and female rats were greater than 1000 mg/kg and 390 mg/kg, respectively (Dubost et al., 1963, MRID 000006643). Signs of toxicity were characteristic of cholinesterase inhibition as described for acute oral toxicity. Deaths occurred within four days.

No further testing is needed.

3. Primary Eye Irritation

There is one supplementary eye irritation study (Dubost et al., 1963, MRID 000006643). It did not follow standard procedures and does not fulfill this data requirment.

Therefore, data are still required.

There are data available for the EC formulation, which demonstrate that phosalone is severely irritating to the eye (Horn et al., 1965, MRID 000006690). The registrant may use this study to fulfill the primary eye irritation data requirement for the technical. However, this would place the technical grade material in Toxicity Category I. In this event the Agency would require changes in the label, including a statement specifying the use of protective goggles.

4. Subchronic Oral Toxicity

Dog studies (Noel et al., 1970, MRID 000006111; Donoso et al.,1967, MRID 000006203; Fournel et al., 1966, MRID 000006684; and Jones et al., 1967, MRID 000006205) indicate that a no-observed-effect-level with respect to plasma cholinesterase inhibition is 25 ppm phosalone in the diet. No systemic effects beside plasma cholinesterase inhibition were observed in dogs given dietary levels as high as 37.5 ppm for four weeks (Noel et al., 1970, MRID 000006111). No other subchronic study clearly characterized a no-observed-effect-level for systemic effects, because lower doses were used (Fournel et al.,1968, MRID 000006684), or because higher doses (100, 200 and 1000 ppm) were administered for a much longer time (two years) without effects (Donoso et al., 1967, MRID 000006203).

A test in a second species (preferably the rat) is also required by the guidelines. Although a rat study (Dubost et al., 1963, MRID 000006643) was conducted, it was limited to male rats and was only five weeks in duration. Also, it did not establish a no-observed-effect-level with respect to blood cholinesterase inhibition in male rats.

However, the rat chronic feeding study (Woodard et al., 1967, MRID 000006202) established a no-observed-effect-level. (See Chronic Feeding Toxicity.) Therefore, there is no need for an additional rat study.

No further testing is required.

5. Subchronic Neurotoxicity

A subchronic neurotoxicity study (Woodard et al., 1966, MRID 000006695) showed that phosalone caused no demyelination at dietary levels up to 500 ppm in chickens treated for 45 days.

No further testing is required.

6. Chronic Feeding Toxicity

Sufficient data on chronic toxicity are available to indicate that phosalone causes no systemic toxicity in rats fed diets containing 0, 25, 50, or 250 ppm for two years (Woodard et al., 1967, MRID 000006202). A no-observed-effect-level was established at 25 ppm phosalone in the diet for rats with respect to red blood cell cholinesterase inhibition.

No further testing is required.

TABLE 1

Summary of acute oral LD_{50} values (mg/kg body weight) for manufacturing-use phosalone

Animal	Sex	LD_{50}	Reference
Rats	Males Females	125 (102-152)[1] 90 (68-119)[1]	Fournel et al., 1968, MRID 000006716
	Male and Female	120 (105-135)	Pasquet et al. 1976, MRID 005007746
	Females	135	Dubost et al., 1963, MRID 000006643
Mice	Unspecified	130 190	Rivett and Davies, 1966, MRID 000006697
	Unspecified	180 435[2]	Dubost et al., 1963, MRID 000006643
Guinea Pig	Unspecified	150	Dubost et al., 1963, MRID 000006643

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[1] 95% confidence intervals are given in parentheses.

[2] Phosalone was administered in an oil solution. All other LD_{50}'s were determined with phosalone in aqueous suspension.

7. Oncogenicity

There are sufficient data to show that phosalone does not have oncogenic effects in rats (see previous section) at dietary levels as high as 250 ppm (Woodard et al., 1968, MRID 000006202) and in mice at dietary levels as high as 150 ppm (Rhone-Poulenc, 1980, MRID GS0027021.) These studies are both lifetime feeding studies.

No further data are needed.

8. Teratogenicity

There are data to demonstrate that phosalone is not fetotoxic or teratogenic in rats (Khera et al., 1979, MRID 005008254) or rabbits (Pasquet, J. and Buisson M., 1969, MRID 000006110) at daily doses as high as 15 or 18 mg/kg, respectively.

These two studies satisfy the minimum data requirement for teratology testing.

9. Reproductive Effects

A three generation reproduction study (Jones et al., 1967, MRID 000006204) partially fulfills the data requirements for reproduction toxicity testing. In this study groups of rats were given diets containing 0, 25, or 50 ppm phosalone. The study was compromised during the second and third generations by the occurrence of a laboratory infection in test animals. In view of the rapid metabolism and excretion (Collins, R.E. and Ings, R.M.J., 1967, MRID 000006977, and Desmoras et al., 1968, MRID 000006715), the lack of teratogenicity or fetotoxicity at high doses, which are approximately 37 to 56 percent of the acute oral LD$_{50}$ in rats (Khera et al., 1979 MRID 05008254 and Pasquet, J. and Buisson, M., 1969, MRID 000006110), and the absence of mutagenic activity in bacteria (Benazet, F. and Cartier, J.R., 1978, MRID GS0027020), the available studies are sufficient to fulfill testing requirements for reproduction toxicity. The no-observed-effect-level for these effects is 50 ppm in the diet (the highest level tested).

10. Mutagenicity

A bacterial assay (Benazet, F. and Cartier, J.R., 1978, MRID GS0027020) and a dominant lethal test in mice (Goldenthal et al., 1978, MRID GS0027019) indicate that phosalone is not mutagenic. Although these studies only partially fulfill the data requirements, the results of the studies on teratogenicity (Khera et al., 1979, MRID 005008254 and Pasquet, J. and Buisson, M., 1969, MRID 000006110), reproduction (Jones et al., 1967, MRID 000006204), and oncogencity (Woodard et al., 1967, MRID 000006202; and Rhone-Poulenc, 1980, MRID GS0027021) indicate that further testing is not necessary. In addition, the rapid metabolism and excretion of phosalone and its metabolites (Collins, R.E. and Ings, R.M.J., 1967, MRID 000006977 and Desmoras et al., 1968, MRID 000006715) further support the decision to waive further testing requirements.

11. Metabolism and Pharmacodynamics

The available data show that phosalone is metabolized rapidly in the rat (Collins, R.E. and Ings, R.M.J., 1967, MRID 000006977 and Desmoras et al., 1968, MRID 000006715). Fifty percent of the administered dose is metabolized and excreted within 24 hours after treatment. Metabolites included the oxygen analogue, diethyldithio- and diethylthionophosphoric acids. The heterocyclic ring is also rapidly degraded to carbon dioxide, accounting for approximately two-thirds of administered radiolabel (in the heterocyclic ring) in the rat (Collins, R.E. and Ings, R.M.J., 1967, MRID 000006977). Most of the remaining activity is excreted in the urine. In vitro studies with liver tissues also show that phosalone is metabolized to its oxygen analogue (Desmoras et al., 1968, MRID 000006715).

Studies with mice demonstrate that 98 percent of the administered dose of phosalone is excreted within 16 hours (Desmoras et al., 1968, MRID 000006715).

Studies with cows given phosalone labeled in the benzene ring showed that the major route of excretion of administered radioactivity is in the urine. Approximately 50 percent was excreted during the first 24 hours following dosing (Craine, E.M., 1974, MRID 000006972 and 000006973). A dermal application of 13.9 milligrams of radiolabeled phosalone was applied to a pig and showed that the chemical is not absorbed through the skin (Craine, E.M., 1974, MRID 000006975).

Studies concerning cholinesterase inhibition are also available. In one study groups of 18 female rats were given a single oral dose of 0, 4, 12, or 36 milligram of phosalone per kilogram body weight (Pasquet et al., 1976, MRID 005007746). Cholinesterase levels were measured at 2, 5, or 24 hours after treatment in six animals from each group. The dose required for 50 percent inhibition (ID_{50}) of the cholinesterase activities are summarized as follows:

	ID_{50} (mg/kg)	
Type	at 2 hours	at 5 hours
Plasma	16.0	16.5
Red blood cell	15.0	10.5
Brain	31	23

In another study by Fournel et al. (1968, MRID 000006716), groups of 18 rats of each sex were given single oral doses of 0, 3, 9, or 27 milligram phosalone per kilogram body weight or 1,3, or 9 milligram oxygen analogue per kilogram body weight. One group of six animals of each sex was sacrificed 1.5, 6, or 24 hours after dosing and cholinesterase activities were measured in the blood (plasma and erythrocytes) and the brain. The investigators stated that peak inhibition was seen between 1.5 and six hours after treatment. The oxygen analogue was shown to be a more potent inhibitor of cholinesterase than the parent compound.

No further testing is necessary for metabolism and pharmacodynamics.

12. Additional Information

There are sufficient data to show that phosalone inhibits blood cells cholinesterase in calves given diets containing 0, 20, 50, 80 or 160 ppm phosalone for eight weeks (Woodard et al., 1967, MRID 000006677). The no-observed-effect-level for this inhibition was 80 ppm. No other toxic effects were observed. Cows receiving diets containing 0, 25, 50 or 100 ppm phosalone for 21 days showed no compound related effects (Totmann et al., 1967, MRID 000006073).

Phosalone in the diets of chickens at 31 or 115 ppm for four weeks decreased egg production to 69.7 percent and 68.9 percent respectively, as compared to 74.4 percent for untreated birds. Egg production in treated birds increased when they were given diets without phosalone. No other effects were noted (McGinnis, C.H., Jr., 1974, MRID 000006976). The no-observed-effect-level was 9 ppm with respect to egg production. No effect on embryonated chicken eggs were noted at doses as high as 1.8 milligrams phosalone per egg (highest dose tested) (Pasquet, J. and Buisson, M., 1969, MRID 000006110).

A study was conducted to determine the effectiveness of antidotes against a lethal dose of phosalone in mice and rats (Rivett, K.F. and Davies, V., 1966, MRID 000006697). One of the antidotes tested was P_2S, which is the chemical name for 1-methyl-pyridyl-2-aldoxine methyl sulphate. It is an analogue of 2-PAM, which is suggested as an antidote for phosalone poisoning on the label. The other antidote tested was atropine. Both chemicals are classified as cholinesterase reactivators and as such are useful in reversing the effects of cholinesterase inhibition caused by phosalone. In this study atropine was administered immediately after dosing, while P_2S was administered when signs of toxicity appeared. P_2S alone was found to be a more effective antidote than atropine alone.

B. Toxicology Profile-End-Use Phosalone

The studies which fulfill or partially fulfill the data requirements for the end-use products are grouped by Guideline requirements and are discussed below.

The requirements for acute dermal toxicity and acute inhalation toxicity have been fulfilled for the EC formulation. These data will also fulfill these data requirements for the WP formulation.

1. Acute Oral Toxicity

Table 2 summarizes the acute oral LD_{50} values for the two formulations, EC and WP. Signs appeared two hours after dosing. Deaths occurred within 24 hours after treatment. Rats given 147 mg/kg or greater had tremors and depression, while doses of 215 mg/kg or greater caused salivation and lacrimation (Scott, W.J. and Beliles, R.P., 1965, MRID 000006688). These results indicate that the formulations of phosalone have high acute oral toxicity, placing it in Toxicity Category II.

No additional testing is required for either formulation.

2. Acute Dermal Toxicity

There are sufficient data to indicate that the acute dermal toxicity of the formulations is moderate (Toxicity Category III). The acute dermal LD_{50} is greater than 2000 mg/kg in male and female rabbits (Horn et al., 1965, MRID 000006689). No overt signs of systemic toxicity or cholinesterase inhibition were seen in rabbits, and only mild erythema was seen in rabbits treated with the 2000 mg/kg dose.

3. Acute Inhalation Toxicity

There are sufficient data to indicate that the acute inhalation toxicity of phosalone formulations is relatively low (Toxicity Category IV) (Beliles, R.P., 1966, MRID 000006981). The acute lethal concentration time (LCT_{50}) was found to be 64 mg hr/liter of air for rats.

4. Primary Eye Irritation

There are data indicating that the emulsifiable concentrate is severely irritating to the eyes of rabbits (Horn et al., 1965, MRID 000006690). Corneal opacity persisted in some of the rabbits for seven days. It should be noted that the treated eyes were not washed after instillation of the formulation.

The Agency will accept this study to fulfill this data requirement, even though it was not conducted for 21 days, as specified in the guidelines. This places the formulation in Toxicity Category I. Changes in the current label should be made, as discussed in Chapter II and the guidance package. However, the registrant may wish to submit additional studies, which are conducted over the 21 day time period. Such studies may result in a lower Toxicity Category.

There are no data available for the WP formulation. Therefore, data are still required.

TABLE 2

Summary of acute oral LD_{50} values (mg/kg) for formulations of Phosalone

Animal	Sex	Formulation	LD_{50}	Reference
Rats	Male and Female	WP	480	US EPA, 1973, MRID GS0027005
	Males	WP	600	US EPA, 1976, MRID GS0027003
	Males	EC	274 (195-385) 1/	Scott and Beliles, 1965, MRID 00006688
	Females	EC	261 (169-403) 1/	
	Male	EC	488	US EPA, 1973, MRID GS0027006
	Females	EC	>480	US EPA, 1972, MRID GS0027004
Mice	Unspecified	EC	160 2/ 190 3/	Rivett and Davies 1966, MRID 00006697

1/ 95% confidence limits

2/ Test material was 13 and 14 months old.

3/ Test material was relatively fresh.

However, the registrant may submit the data from the EC formulation. Again, this would place the WP in Toxicity Category I. The appropriate changes in the label would also be needed, including a statement concerning the use of goggles.

5. Additional Information

There is one study of antidotes in rats and mice which used lethal doses of the EC formulation administered orally (Rivett, K.F. and Davies, V., 1966, MRID 000006697). The results are similar to those described above for the manufacturing use formulation.

C. Toxicology Profile-Oxygen Analogue

1. Acute Oral Toxicity

The oral LD_{50} of the oxygen analogue in female rats was 21 mg/kg with 95 percent confidence limits of 12 to 28 mg/kg (Pasquet et al., 1976, MRID 005007746). In male rats the oral LD_{50} was found to be 36 mg/kg with a confidence interval from 29 to 44 mg/kg, while that for female rats was 20 mg/kg with a confidence interval from 15 to 29 mg/kg (Fournel et al., 1968, MRID 000006716). Signs of toxicity were similar to those in animals treated with phosalone and deaths were seen within 24 hours of treatment with the analogue.

Additional information is available concerning the oral LD_{50} in mice. Fournel et al. (1968, MRID 000006716) reported 35 mg/kg with a 30 to 41 mg/kg confidence interval in males and 40 mg/kg with a 33 to 49 mg/kg confidence interval for females. Societe des Usines Chimique Rhone-Poulenc (1968, MRID 000006674) reported 32 mg/kg. In both cases the signs of toxicity were indicative of cholinesterase inhibition.

2. Acute Dermal Toxicity

A dermal LD_{50} in rats of 380 mg/kg was reported by Pasquet et al. (1976, MRID 005007746) with no further information. These data suggest that the analogue is approximately five times more toxic than the technical or the EC formulation.

D. Hazard Assessment for Manufacturing and End-Use Products

The phosalone exposure profile (refer to Chapter V) provides that maximum exposure will occur with those involved in direct mixing, loading, and application. The principal routes of exposure may be anticipated to be dermal and inhalational; the latter coming from applicator exposure to spray mist. As noted above, the acute toxicity of phosalone falls within Categories I through IV, depending upon route of exposure and formulation. The WP and EC acute oral toxicity is relatively high, while acute dermal and inhalation toxicities are moderate to low. In addition, the acute oral and dermal toxicities of phosalone-oxon is high. The primary toxic effect of phosalone is its cholinesterase inhibition. Phosalone, as demonstrated in a study with the EC formulation, is also a severe eye irritant causing persistent corneal opacity, if the chemical is not washed from the eye. The Agency believes that the acute hazards resulting from exposure to phosalone are mitigated by those precautionary measures prescribed by the product labeling requirements as outlined in Chapter II.

Although the Agency does not possess the full complement of chronic toxicity data as required by the Guidelines, those data available for Agency review do not indicate any potential for oncogenic, mutagenic, teratogenic, or reproductive effects. The Agency, therefore, believes that phosalone, when used according to label directions, presents no chronic hazard.

E. Data Gaps

Data gaps for acute inhalation toxicity, primary dermal irritation, primary eye irritation, dermal sensitization, and acute delayed neurotoxicity should be filled for manufacturing-use phosalone. Data for primary dermal irritation and dermal sensitization are still needed for the EC and WP formulations. Data concerning primary eye irritation are still needed for the WP formulation.

CHAPTER VII. RESIDUE CHEMISTRY

A. Residue Chemistry Profile
B. Data Gaps

A. Residue Chemistry Profile

1. Metabolism in Plants

The metabolism and degradation of phosalone follows a pattern typical of that of phosphorodithioate esters; i.e. oxidation to the phosphate (oxygen analogue), hydrolysis and conjugation of the benzoxazolone nucleous with a gylcoside and further elimination of this conjugate (FAO Working Party of Experts on Pesticide Residues, 1973, MRID 005013895). Phosalone has been found to directly hydrolyze although oxidation to the oxygen analogue and then hydrolysis of this metabolite is the more predominant path of degradation (Societe des Usines Chimiques Rhone-Poulenc, 1968, MRID 000006675). Experiments with de-ethylation reactions have shown that it is very unlikely that de-ethylation of phosalone in plants will occur (Demoras et al., 1968, MRID 00006791).

The oxygen analogue of phosalone was detected in treated plants but always at minute quantities usually about one percent of the total residue and never more than ten percent (Desmoras et al., 1968, MRID 000006791). After hydrolysis of phosalone or its oxygen analogue, the diethyldithio- or thionophosphoric acid leads to the formation of orthophosphoric acid (Desmoras et al., 1966, MRID 000006386 and Winterlin et al., 1974, MRID 005009309). The benzoxazolone nucleus of the molecule or 6-chlorobenzoxazolone has never been detected by itself. However it was found as a conjugate of a glycoside; i.e. [(6-chloro-2-benzoxazolone)3-yl]-1-glucopyranose (Desmoras et al., 1968, MRID 000006791).

Phosalone is not regarded as "systemic"; however, when applied to the soil it will be absorbed and translocated by some plants (Kovaleva, E.S. and Talanov, G.A., 1977, MRID 005014688). It has been noted that grapes treated with phosalone showed absorption of phosalone into the pulp instead of being retained on the skin (Nalbandyan, R.A., 1975, MRID 005016356).

A study with potato plants, where the leaves had been treated with ^{14}C-phosalone, showed that 99.5 percent of the radioactivity remained at the treatment area. The formed tubers contained less than 0.01 percent of radioactivity 14 days after the treatment. This indicates that there is no translocation of phosalone out of the treated area (Ambrosi et al., 1974, MRID 000006125).

Accordingly it is understood that the nature of the residue resulting in plants from a treatment of phosalone is as follows: phosalone per se, its oxygen analogue (usually one to ten percent of the total residue) and its hydrolysis products and [(6-chloro-2-benzoxazolone)-3-yl]-1-glucopyranose present only in trace amounts. The metabolism and degradation pathways of phosalone in plants are well defined and no further studies are necessary.

2. Metabolism in Animals

In a study with animals (Desmoras et al., 1968, MRID 000006715)), rats and mice were fed one dose of phosalone at 35 mg/kg and 50 mg/kg, respectively. The animals were sacrificed at varying time intervals after ingestion. Samples of urine, feces and of the whole body were taken for analysis. Over 99 percent of the ingested phosalone "disappeared" within 24 hours. Analysis also showed the absence of any oxygen analogue of phosalone and 6-chlorobenzoxazolone residues. Thus, neither phosalone, its oxygen analogue, nor 6-chlorobenzoxazolone were found in the tissues or excreta.

Important quantities of diethyl dithio- and thiono-phosphoric acids were detected in the animal body, urine and feces indicating there was hydrolysis of the phosalone molecule. The 6-chlorobenzoxazolone residue was not detected.

A metabolism study with dairy cattle (Craine, E.M., 1975, MRID 000006974) was as performed to identify residues in milk and urine following the administration of a single dose of ^{14}C- benzene ring labeled phosalone. No tissues were analyzed. The major route of elimination of phosalone residues was reportedly via the urine (86-94 percent); the feces accounted for about six percent of the remainder. Only 0.3 percent of ^{14}C - activity appeared in the milk (i.e. 0.19 ppm.) Almost all (93-100 percent) of the administered ^{14}C - dose was recovered within 104 hours.

In the urine about two percent of the ^{14}C in the dose was excreted as phosalone per se or its oxygen analogue. Two major urinary metabolites were isolated and determined to be 2-oxo-3-mercaptomethyl-6-chlorobenzoxazole and 2-amino-5-chlorophenol. The 2-oxo-3-mercaptomethyl-6-chlorobenzoxazole is formed by hydrolytic cleavage of the S-P bond of phosalone and 2-amino-5-chlorophenol could subsequently be formed by the hydrolytic opening of the benzoxazole ring. Another 15 compounds containing low levels of radioactivity were present; however they were not identified.

In milk less than 10 percent of the 0.19 ppm ^{14}C - activity present was identified as phosalone or its oxygen analogue (<0.02 ppm). The major metabolites found were 2-amino-5-chlorophenol (0.08 ppm) and 2-oxo-3-mercaptomethyl-6-chlorobenzoxazole (0.03 ppm). Other compounds containing radioactivity were also present but at levels too low to warrant identification (0.03 ppm).

The presence of these two compounds in milk caused the Agency to request Rhone-Poulenc to submit additional methodology capable of measuring all chlorobenzoxazole-and chlorophenol moiety-containing metabolites. Such methodology must be able to measure the chlorophenol metabolite(s) as separate entities. Residue studies submitted in December of 1980 by Rhone-Poulenc concerning meat, milk, poultry and eggs in conjunction with a pending registration action for the use of phosalone in or on alfalfa showed the possible presence of residues of secondary phosalone metabolites. These studies are still awaiting final review.

Metabolism data indicate that phosalone per se is the primary residue of concern after use of phosalone on raw agricultural crops. The metabolism of phosalone in animals is considered, however, to be adequately defined at the present time.

3. Analytical Methodology

a. Agricultural Crops

The following references discuss chronologically the development of the analytical method which was used for the collection of the majority of the residue data on the agricultural crops subject to this registration Standard: Desmoras, J., 1965, MRID 005016979; Guardigli, A., 1964, MRID 000006383; Guardigli, A., 1968, MRID 000006703 and GS0027010; Guardigli, A. and Melkesian, B., 1968, MRID 000006083; Guardigli et al., 1967, MRID 000006678; Guardigli et al., 1971, MRID 005008180; Laurent et al., 1967, MRID 000006700 and Societe des Usines Chimiques Rhone-Poulenc, 1968, MRID 000006701. This method, known as Rhone-Poulenc's Method No. 54A, was also adopted as the regulatory enforcement method and is therefore published in the Pesticide Analytical Manual, Volume II, Section 120. 263.

Method No. 54A is the main method which determines the concentration of the parent compound present and consists of a gas chromatographic procedure. Thin layer chromatographic (TLC) methods (Rhone-Poulenc's Methods No. 54D and 54E) are employed for the determination of the oxygen analogue of phosalone, the metabolite [(6-chloro-2-benzoxazolone)-3-yl]-1-glucopyranose and may also be used to confirm the presence of the parent compound.

In method No. 54A the residue is extracted from the crop with acetone and buffered. The solvent is evaporated. The aqueous phase is extracted with methylene chloride. The extract is cleaned up by liquid partition on a Florisil column. After elution with ethyl acetate and evaporation, the residue is dissolved in benzene. The amount of pesticide is determined with the use of a gas chromatograph utilizing electron capture system. This method is supplemented by a TLC procedure for confirmatory purposes.

Recoveries obtained in a method try-out on apples ranged from 74-91 percent at 10 ppm and 95 percent at 20 ppm. The sensitivity of the method is 0.1 ppm.

Overall, recoveries obtained at fortification levels from 0.25-2.0 ppm averaged 92.5 percent.

When thin layer chromatographic methods 54D and 54E are employed, the final cleaned-up extract in benzene is spotted versus standard solutions on a TLC plate coated with Silico Gel GF254. The plate is developed in the proper elution medium. After air drying, the plate is sprayed with a 2N sodium hydroxide solution and heated for five minutes at 120°C. After cooling, the plate is sprayed with a specific detection reagent. Phosalone as low as 0.1 ppm in the presence of other pesticides can be detected.

b. Meat and Milk

For the analysis of meat and milk samples, a modification of method No. 54A is used. The modification consists of a change in the clean-up procedure. This modified procedure is known as method 54C (Guardigli, A., 1967, MRID 000006129; 1971, MRID 000006762; 1973, MRID 000006105.) Although this method will determine both phosalone and its oxygen analogue, this method was tried-out in one of EPA's laboratories for phosalone only in beef fat. Samples fortified at 0.25 ppm and 0.50 ppm of phosalone produced recoveries ranging from 88-92 percent and 92-98 percent, respectively. The controls were <0.005 ppm. The method as tried out by Rhone-Poulenc's Laboratory for milk at fortification levels of 0.1-0.5 ppm of phosalone gave recoveries from 80-99 percent. Recoveries from tissues at levels from 0.2-0.5 ppm ranged from 83-97 percent. Control values were not more than 0.05 ppm in animal tissues and <0.0255 ppm in milk. The sensitivity of the method is estimated to be 0.1-0.2 ppm for meat and milk.

Accordingly it is concluded that adequate methodology is available for the collection of residue data and for enforcement purposes for measurement of combined residues of phosalone and its oxygen analogue in and on raw agricultural commodities including meat and milk. Methods for phosalone published in the Pesticide Analytical Manual are adequate for enforcement purposes. As previously mentioned, however, new methods are currently being reviewed in a pending registration action concerning the use of phosalone in or on alfalfa.

4. Residues in Plants and Animals

The reported residue studies overall reflect the registered uses of phosalone on raw agricultural crops, processed foods, by-products and feed items. Feeding studies reflecting residues of phosalone in large animals and poultry were adequate in exhibiting the possible transfer of residues of phosalone to meat, milk, poultry and eggs.

The established tolerances for residues of phosalone which may result from the registered uses are found adequate for the raw agricultural commodities as well as the processed foods, by-products and feed items. The established tolerance (0.25 ppm) for meat, fat and meat by-products of cattle, goats, hogs, horses and sheep is adequate to cover possible residues of phosalone which may transfer to these commodities.

Residues in milk, poultry and eggs, resulting from the registered uses of phosalone are considered representative of category three of section 180.6(a); i.e., it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues.

It is possible that the 0.25 ppm tolerance for residues of phosalone in the meat, fat, and meat by-products of cattle, goats, hogs, horses and sheep, may have to be raised in value and include particular metabolites present in tissues and milk, pending a registration action for phosalone use in or on alfalfa. (Please refer to chart in Chapter III for a listing of the citations, which are grouped by the crop studied.)

5. Storage Stability

Several studies containing information on the storage stability of samples of technical and formulated phosalone show that phosalone is very stable (Desmoras et al., 19??, MRID 000006968; Klisenki, M.A. and Pis'mennaya, M.V., 1973, MRID 005014548; Laurent et al., 1965, MRID 000006698 and Rhodia, Inc., 19??, MRID 000006113). (See Chapter IV, Product Chemistry, Physical/Chemical Properties for a detailed discussion.)

6. Tolerance Levels

a. Present U.S. Tolerances

1). Raw Agricultural Commodities

According to 40 CFR 180.263 tolerances for residues of phosalone, in or on raw agricultural commodities are as follows:

50 ppm in or on almond hulls.
25 ppm in or on artichokes.
15 ppm in or on apricots, cherries, nectarines, peaches, and plums (fresh prunes).
10 ppm in or on apples, grapes, and pears.
3 ppm in or on citrus fruit.

0.25 ppm in the meat, fat, and meat by-products of
cattle, goats, hogs, horses, and sheep.
0.1ppm (negligible residue) in or on almonds
and potatoes.
0.05 ppm (negligible residue) in or on brazil
nuts, bush nuts, butternuts, cashews, chestnuts, filberts,
hazelnuts, hickory nuts, macadamia nuts, pecans and walnuts.

2). Processed Foods

Also according to 21 CFR 561.300, tolerances for residues of phosalone are established in or on the following processed foods, when present therein as a result of the application to growing crops:

85 ppm in or on dried apple pomace.
45 ppm in or on dried grape pomace.
12 ppm in or on dried citrus pulp.

In addition, according to 21 CFR 193.340 tolerances are established for residues of the insecticide phosalone in or on the following processed foods when present therein as a result of application to the growing crops;

40 ppm in or on dried prunes.
20 ppm in or on dried raisins.
8 ppm in or on dried tea.

b. CODEX Tolerances

A list of suggested maximum limits in ppm for residues of phosalone on an international basis is exhibited below.

These limits were a result of joint meetings on Pesticides Residues in 1972, 1975, and 1976. The Acceptable Daily Intake (ADI) was calculated to be 0.006 mg/kg body weight.

CODEX Tolerances

Commodity	Maximum (ppm) for Phosalone Residues
Apples	5
Beet roots	2
Broccoli	1
Brussels Sprouts	1
Cabbage	1
Cherries	10
Chestnuts (Shell-free Basis)	0.1(*)
Citrus Fruit	1
Cucumber	1
Grapes	5
Hops (Dried)	2
Lettuce	1
Peaches	5
Pears	2
Peas	1
Pecans (Shell-free Basis)	0.1(*)
Plums	5
Potatoes	0.1(*)
Rapeseed	0.1(*)
Sheep, Fat	0.5
Sheep, Carcass Meat	0.05(*)
Strawberries	1
Tomato	1

(*)Level at or about the limit of determination

A comparison of the U.S. tolerances with the CODEX tolerances indicates that most of the U.S. tolerances are remarkably higher than the CODEX tolerances. A reassessment of the U.S. tolerances indicates that it is impractical to lower the U.S. tolerances due to the level of residues that result from the registered use in the U.S.

Some CODEX tolerances are higher, however. For example, the CODEX tolerance for residues of phosalone in the fat of sheep (0.5 ppm) is twice that of the U.S. (0.25). This is because the CODEX tolerance reflects residues resulting from a "sheep-dip" use, a use which is not registered in the U.S.

The U.S. tolerance for animal fat reflects phosalone residues resulting from feeding the animals crops treated with phosalone; this use is not considered under the international tolerance. The U.S. tolerance for phosalone in meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep is being reevaluated due to the pending registration action for use in or on alfalfa.

The CODEX tolerance of 0.1 ppm for pecans and chestnuts (nuts) is also higher than that of the U.S. tolerance of 0.05 ppm for nuts (except almonds). Both tolerances are based on the sensitivity of the method used. The U.S. tolerance is a negligible tolerance and could be made consistent with the CODEX tolerance (i.e. 0.1 ppm) for the nut grouping (except almonds) as defined under Title 40, section 180.34(f), which states in part,

> "It may be possible to make a reliable estimate of negligible residues of pesticide chemicals to be expected on each commodity in a designated grouping on the basis of data on a representative number of commodities listed in the following designated groups."

The commodities listed for nuts include Brazil nuts, bush nuts, butternuts, cashews, chestnuts, filberts, hazelnuts, hickory nuts, macadamia nuts, pecans, and walnuts.

A change in the tolerance to a higher level, however, is dependent upon a recalculation of the Theoretical Maximum Residue Concentration (TMRC). The Agency recalculated the TMRC and found that it would be appropriate to make the U.S. tolerance for nuts (except almonds) consistent with the CODEX tolerance of 0.1 ppm. The result is discussed in Chapter 2 under the Tolerance Reassessment Section.

7. Special Local Need Registrations

In 1980, additional uses for the application of phosalone by aircraft to almonds, grapes, stone fruit and walnuts were granted by California under Section 24 (c) of FIFRA, which provides for a state to obtain additional uses to meet special local needs. The maximum use per acre for all crops is the same as for those applied by ground equipment except the spray volume for the aerial application can be reduced to a minimum of 20 gallons of water. We have reviewed the data reflecting the residues resulting from the ground applications and in conjunction with the fact that F.D.A. Market Basket Surveillance data report residues of phosalone considerably below the established tolerances; it is concluded that the registered Section 24 (c) uses are in compliance with the respective established crop tolerances.

B. Data Gaps

No generic data gaps were identified with regard to Residue Chemistry.

CHAPTER VIII: ECOLOGICAL EFFECTS

A. Ecological Effects Profile
B. Hazard Evaluation
C. Data Gaps

A. Ecological Effects Profile

Phosalone, as noted earlier in the Use Summary section of Chapter V, is an insecticide and miticide applied to agricultural and commercial ornamental crops. It may be applied by ground or aerial equipment to agricultural sites and by ground equipment to ornamentals. As a result of these methods of application, some potential exists for the exposure of nontarget terrestrial and aquatic organisms.

1. Birds and Aquatic Invertebrates

In relation to the toxicity of phosalone to birds and aquatic invertebrates, limited data are available. However, these studies are considered inadequate, because they failed to meet guideline requirements. It is thus not possible to assess phosalone's toxicity to these nontarget organisms. Therefore, data are still required.

2. Fish

With respect to the toxicity of phosalone to fish, the available data indicate that it may be highly toxic to both warmwater (McCann, J.A. and Jasper, R.L., 1972, MRID 005009810; USDA, 1969, MRID GS0027002) and coldwater fishes (USDA, 1969, MRID GS0027001). The USDA study (MRID GS0027001) reports a 96 hour LC_{50} of 0.92 ppm for coldwater fishes. This study was conducted with a 34.8 percent active ingredient formulation and characterizes this formulation as being highly toxic to coldwater fishes. The studies concerning the warmwater fishes (MRID 005009810 and GS0027002) were also conducted with the 34.8 percent active ingredient formulation. These studies did not report an LC_{50} value, but did indicate high toxicity. However, the proposed guidelines require that the studies be conducted with the technical product, in order to evaluate the effect of the chemical itself on fishes. Studies performed with technical material facilitate extrapolation for all formulations. Therefore, data are still required with technical phosalone on both warmwater and coldwater fishes.

3. Plants

The data base concerning the toxicity of phosalone to nontarget plants and microorganisms is somewhat limited. Information on the effects of phosalone applied at the recommended rates on citrus, stone fruits, nuts, apples, grapes and potatoes is available. These data show no adverse effects on the plants tested.

Several vegetables for which phosalone is not registered were tested under greenhouse conditions and showed injury. Cucumber, however, was the only plant tested under both greenhouse and field conditions, and displayed no phytotoxic symptoms when treated at one pound active ingredient per acre for the field test. This was twice the rate applied in the greenhouse study. The results from the field study reflect the potential exposure of plants to phosalone more accurately, and the Agency, consequently, assumes that the affected vegetables would be more tolerant in the field.

The label indicated a potential for injury on roses, although no valid studies were received to confirm this.

Although the studies mentioned above were not conducted under the specifications of the proposed guidelines (40 FR 72910; November 3, 1980), the Agency has determined that the studies, in aggregate, provide sufficient information to fulfill the data requirement for vegetative vigor for dicotyledonous plants. These studies adequately describe the phytotoxic effects of phosalone to these plants. (Please refer to the Chapter III charts for ecological effects for the citations.) To completely fulfill this data requirement, however, data must still be submitted for representative monocotyledonous plants. The data requirements for effects on seed germination, algae, and aquatic macrophytes must also be met, because no studies were either submitted or located in the literature.

4. Soil and Terrestrial Invertebrates

With respect to phosalone's toxicity to nontarget soil and terrestrial invertebrates, the available information shows that the adverse effects of phosalone to phytoseiid predaceous mites are highly variable and species specific (Croft, B.A. and Stewart, P.G., 1973, MRID 005009346; Croft, B.A. and Nelson, E.E., 1972, MRID 005009345; Karg, W., 1978, MRID 005020178; Nelson et al., 1973, MRID 005005773; Watve, C.M. and Lienk, S.E., 1975, MRID 005013359; Watve, C.M. and Lienk, S.E., 1976, MRID 005014275).

Available information indicates that phosalone is moderate in toxicity to honey bees, Apis mellifera by either direct spray or residual contact (Atkins, E.L. and Anderson, L.D., 1967, MRID 000006654; Atkins et al., 1970, MRID 000006653; Atkins et al., 1973, MRID 000006652; Grahame, R.E., 1967, MRID 000006657; Smyth, E.P. and Johansen, C., 19??, MRID 000006793). In addition, a residual contact test for wild bees was conducted with the leafcutter bee, Megachile pacifica, and the alkali bee, Nomia melanderi (Smyth et al., 19??, MRID 000006793) and low toxicity was demonstrated. This low to moderate toxicity to pollinators may be mitigated by restricting application to times when bees are not actively foraging. See Chapter II for appropriate label statements.

Although these data concerning nontarget soil and terrestrial invertebrates are quite limited, they appear adequate for current hazard labeling needs. Additional studies may, however, be required upon the promulgation of the Guidelines Subpart L, Hazard Evaluation: Nontarget Insects.

B. Hazard Assessment

Due to the limited amount of information available, a detailed hazard assessment for wildlife cannot be made at this time. There is an indication that phosalone does not present a serious hazard to dicotyledonous plants. There is also an indication that phosalone may be highly toxic to warmwater and coldwater fishes and low to moderately toxic to pollinators.

C. Data Gaps

Tests to assess the ecological effects of phosalone are required, with the exception of the vegetative vigor requirement for dicotyledonous plants. Please refer to the data charts in Chapter III for the specific requirements.

IX. CASE BIBLIOGRAPHY

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature. The bibliography is divided into two sections: (1) citations that contributed information useful to the review of the chemical and are considered to be part of the data base supporting registrations under the standard and (2) citations that have been examined and judged to be inappropriate for use in developing the standard.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit numeric identifier. This number is unique to the citations and should be used at any time specific reference is required. This number is called the "Master Record Identifier" or "MRID". It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submissions:

   (1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

   (2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

   (3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative

position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th,123456-AA.

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